

Submission Report**eRadHealth Menu**

Introduction

Role

What is your role?

!*

Consultant

Information:

The following screen provides several options for you to accurately define what type of eSubmission you intend to create for FDA. Below are explanations of your options. Please feel free to review this screen, advance to the next screen and view the picklists, but if you're confused, come back to read this screen again to be certain you are selecting the correct report or correspondence type you want to create.

Submission Information

Step 1

Use the radio buttons to identify the type of submission you are preparing. (Supplements should be prepared using the same document type as the original submission.)

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.) !*

(•) Radiation Safety Report (Product) Report (21 CFR 1002.10)
() Annual Report (21 CFR 1002.13)

	☐ Laser Light Show Documents (all relevant documents) (21 CFR 1040.11(c)) ☐ Correspondence ☐ Variance Request (General, not Laser Light Show) (21 CFR 1010.4) ☐ Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) ☐ Abbreviated Report (21 CFR 1002.12)
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Step 2	After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list.
What Type of Product is this Radiation Safety Report about? !*	
Laser Products (Includes Projection Systems)	
What Type of Product is this Annual Report about?	
What Laser Light Show Document are you filing?	
What Type of Correspondence is this?	

What Type of Product is this Variance Request about?

Manufacturer Data

Burden to Industry

Manufacturer Responsible for Product Compliance

Note:

This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.

Be sure to enter address information for each tab below:

Select the Manufacturer's address from the Establishment Address book: *

Establishment Information:

Establishment Name	DONGGUAN THUNDERLASER INDUSTRIAL CO., LTD
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Division Name	
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Home Page	
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Physical Location:

Address	Room 1101, Building 3, No.68, Xingzhou Road Shatian Town Dongguan, Guangdong, 523991, CHN
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Telephone Number	86-138-25738103
Fax Number	86-769-88661929
<i>Mailing Location:</i>	
Address	Room 1101, Building 3, No.68, Xingzhou Road Shatian Town Dongguan, Guangdong, 523991, CHN
Telephone Number	86-138-25738103
Fax Number	86-769-88661929

Responsible Individual

<i>Note:</i>	<i>The responsible individual is the highest level and most responsible individual affiliated with this establishment.</i>
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Select the Responsible Individual from the Contact Address book:
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*

<i>Contact Information:</i>

Contact Name	Ms. King Chen
Occupation Title	General manager
Email Address	thunderlaser@sina.com

<i>Establishment Information:</i>

Establishment Name	DONGGUAN THUNDERLASER INDUSTRIAL CO., LTD
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Division Name	
<i>Physical Location:</i>	
Address	Room 1101, Building 3, No.68, Xingzhou Road Shatian Town Dongguan, Guangdong, 523991, CHN
Telephone Number	86-138-25738103
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Manufacturer's Reporting Official

<i>Note:</i>	<i>This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes in testing and quality control procedures submitted to FDA must be signed by this individual.</i>
Select the Reporting Official from Contact Address book: *	
<i>Contact Information:</i>	
Contact Name	Ms. King Chen

Occupation Title	General manager
Email Address	thunderlaser@sina.com
<i>Establishment Information:</i>	
Establishment Name	DONGGUAN THUNDERLASER INDUSTRIAL CO., LTD
Division Name	
<i>Physical Location:</i>	
Address	Room 1101, Building 3, No.68, Xingzhou Road Shatian Town Dongguan, Guangdong, 523991, CHN
Telephone Number	86-138-25738103
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Fax Number	86-769-88661929

Report Submitter

Note:	<i>The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. Documents or submissions such as this one that are</i>
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	<i>prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.</i>
Select the Submitter from the Contact Address book: *	
<i>Contact Information:</i>	
Contact Name	Mr. David Jia
Occupation Title	Engineer
Email Address	davidjia168@126.com
<i>Establishment Information:</i>	
Establishment Name	Shenzhen Junhaicheng Technology Co., Ltd
Division Name	
<i>Physical Location:</i>	
Address	619, TheOne Pioneer Park, No. 247 Xin'an Section of Guangshen Road, Xin'an, Bao'an Shenzhen, Guangdong, 518000, CHN
Telephone Number	86-755-86097442
Fax Number	86-755-86097448
<i>Mailing Location:</i>	
Address	619, TheOne Pioneer Park, No. 247 Xin'an Section of Guangshen Road, Xin'an, Bao'an Shenzhen, Guangdong, 518000, CHN
Telephone Number	86-755-86097442
Fax Number	86-755-86097448

<i>Comments:</i>	
Internal Reference Number:	

Parent Establishment

Is there a parent establishment?	*	No
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Select the Parent Establishment and Contact from the Contact Address book:	
<i>Contact Information:</i>	
Contact Name	
Occupation Title	
Email Address	
<i>Establishment Information:</i>	
Establishment Name	
Division Name	
<i>Physical Location:</i>	
Address	
Telephone Number	
Fax Number	

<i>Mailing Location:</i>	
Address	
Telephone Number	
Fax Number	

Manufacturer Designated United States Agent

<i>Note:</i>	<i>Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.</i>
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Is there a United States agent that has been designated by the manufacturer?	*	Yes
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Written Agreement

Importer

Item: 1

Select the Importer from the Contact Address book:

Contact Information:

Contact Name	Mr. Clay Luttrell
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Occupation Title	
Email Address	
<i>Establishment Information:</i>	
Establishment Name	THUNDER LASER USA LLC
Division Name	
<i>Physical Location:</i>	
Address	9980 FM 346 E Whitehouse TX, 75791
Telephone Number	903-312-8591
Fax Number	903-312-8591
<i>Mailing Location:</i>	
Address	9980 FM 346 E Whitehouse TX, 75791
Telephone Number	903-312-8591
Fax Number	903-312-8591

Additional Manufacturing Locations

Item: 1

<i>Note:</i>	<i>If any of the products certified in this report are manufactured at locations other</i>
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	<i>than listed in the Manufacturer Responsible for Product Compliance section, then the names, addresses, and FDA registration numbers should be provided. In addition any codes used on labels to identify a manufacturing location must be provided. Each factory location must assure all production procedures are followed identically step by step as provided in this report. If the procedures are not the same then separate reports should be filed.</i>
Select the Manufacturer Address from the Establishment Address book:	
<i>Establishment Information:</i>	
Establishment Name	DONGGUAN THUNDER LASER EQUIPMENT CO., LTD
Division Name	
Home Page	
<i>Physical Location:</i>	
Address	Room 1101, Building 3, No.68, Xingzhou Road Shatian Town Dongguan, Guangdong, 523991, CHN
Telephone Number	86-138-25738103
Fax Number	86-769-88661929
<i>Mailing Location:</i>	
Address	Room 1101, Building 3, No.68, Xingzhou Road Shatian Town Dongguan, Guangdong, 523991, CHN
Telephone Number	86-138-25738103
Fax Number	86-769-88661929

Comments:

Code used on identification labels:

Product Data

Product and Model Identification

Product Type Reported

Category	MATERIAL PROCESSING LASER PRODUCTS (47)
Product Code	LASER CUTTER (RFE)
Performance Standard	LASER PRODUCTS. (1040.10)
If Other, provide a category name for this specific product.	

Report Information

Is this the first time you've submitted a report on the particular type of product* selected in the Product Type Reported section?	Yes
Since this is not the first time you've reported on this type of product, then is this a report supplement to a previously reported model family?	
Provide the Accession Number of the original report for which this is a supplement:	

(Note: Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc. See Accession number description below.)

Are you requesting a new variance, a renewal, extension or amendment to * a previous variance? No

Stop: If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request (General, not Laser Light Show)" as your Type of Submission in the Submission Information Screen. If you select "Variance Request (General, not Laser Light Show)" you must select the product for which you are requesting a variance with the pick list in the bottom section of the screen.

Special Considerations

Information: If this product will require a formally approved Variance from a certain performance requirement, you will need to complete two Reports for FDA, both (1) this Radiation Safety Report (RSR) on this product, and (2) a Variance Request report. This eSubmitter software application package includes a general Variance Request form as well as the specific Laser Light Show Variance Request form. Both the Product RSR file and the appropriate Variance Request Correspondence file must be submitted to CDRH following the regular files packaging procedures in this application. Both may be transferred to the same CD or submitted via the FDA ESG to submit to the FDA/CDRH.

In addition, any Variance Request form must be printed out and the signed hard-copy sent to FDA's Division of Dockets Management at:

Division of Dockets Management (HFA-305)
Food and Drug Administration

	5630 Fishers Lane Rockville, MD 20852 <i>NOTE: There is no need to send a copy of the CD to Division of Dockets Management.</i>
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Noncompliances or Defects

Does this document or any of its attachments contain:		
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A notification of noncompliance or defect?	*	No
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You may provide an explanation and/or attach a document here:		
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Details	
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Responses to Noncompliances or Defects
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Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?		
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A refutation of noncompliances or defects identified to your firm?	*	No
--	---	----

A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)?	*	No
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Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production?	*	No
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Note:	<i>If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be</i>
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	<i>submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."</i>	
A description of any design changes that correct noncompliances for future production? *		No
<i>Note:</i>	<i>If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report . Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.</i>	
You may add an explanation and/or attach a document here:		
Details		

Exemption Requests

Does this document or any of its attachments contain:		
Exemption of a product for government use from a standard (21 CFR 1010.5)?	*	No
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)?	*	No
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)?	*	No
Request for approval of alternate labeling?	*	No
Application for alternate test procedures (21 CFR 1010.13)?	*	No
You may provide an explanation and/or attach any relevant documents here:		

Variance Requests

Information:	<i>Please note: in addition to responding to these questions below, a separate General Variance Request or Laser Light Show Variance Request form must be completed and submitted to CDRH, with a hard copy sent to FDA's Division of Dockets Management as instructed below for any variance request. The information requested on this screen does not constitute the full structured content of the variance request. The 2 types of Variance forms can be created in eSubmitter by selecting the appropriate Variance submission type under the eRad Health Menu section of this application.</i>
Message:	<i>Click the plus sign to list the requirements from which you are requesting a variance.</i>
This submission includes an application for a variance from certain requirements.	
Item	No Information Provided.
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	
Stop:	<i>For all Variance requests, two submissions must be made to the FDA.</i> <i>The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to:</i> <i>U.S. Food and Drug Administration Center for Devices and Radiological Health Attn: eSubmitter Team Document Mail Center - WO66-G609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002</i> <i>Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to:</i>

	<i>Food and Drug Administration</i> <i>Division of Dockets Management (HFA-305)</i> <i>5630 Fishers Lane, Room 1061</i> <i>Rockville, MD 20857</i>
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Responses to Communications from FDA

Does this document or any of its attachments contain:

A response to an FDA inspection?	*	No
What was the date of the inspection?		
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	*	No
What was the date of the Warning Letter or other notification letter?		
A response to a report review inquiry from the CDRH (the inquiry may have been in the form of a letter, email, or phone call)?	*	No
What was the date of the inquiry?		
A response to any other communication from FDA?	*	No
What was the date of the communication?		
Provide an explanation:		

Additional Information

Here's your opportunity to add anything else to this submission that you want to tell the FDA!

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.

File Attachment 1	attachment 3.1 user manual 250927
File Attachment 2	copy of agreement with US agent 250927
File Attachment 3	declaration of conformity for models difference 250927
Details	This product is a model family laser cutter & Laser engraver, and it belongs to a Class 1 laser product, during normal operation, the 10.6um CO2 laser radiation and the 650nm guidance laser radiation is inclosed by the interlocked protective housing. A copy of agreement of specified US agent is attached with this subchapter.

Private Labeling

Is the product sold by other companies under different brand names?

*

No

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.

If it has not been submitted yet, or if your device is exempt from premarket clearance or approval, please provide an explanation. The device regulations can be found in 21 CFR 807 - device manufacturer registration and device listing.

Laser Product

PART 1: DEFINITIONS

PART 2: PRODUCT AND MODEL IDENTIFICATION

2.1 Model Designation

Note: Report the model name and/or number, model family, brand name, or other designation of the product. If reporting a model family, provide the model designation of each model. If you do not use a model family or brand name, leave the field blank.

Model Designation (Names and/or Numbers):

*

Item	Model Name	Family Name	Brand Name
Item 1	Thunder Bolt, Thunder Bolt Plus	Laser cutter & Laser engraver	THUNDER LASER
Item 2	Thunder Bolt Pro 22, Thunder Bolt Pro 32	Laser cutter & Laser engraver	THUNDER LASER
Item 3	Thunder Bolt Plus 24, Thunder Bolt Pro 36	Laser cutter & Laser engraver	THUNDER LASER

2.2 Approval of Alternate Means

Does this document or any of its attachments contain:

An application for approval of alternate means of providing the equivalent or superior protection that a required performance feature or labeling would provide (this is applicable to the beam attenuator requirements and alternate labeling)? *	No
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What requirement are you requesting an approval of alternate means from?

Provide an explanation:

2.3 Product without a Laser

Is it a product that does not incorporate a laser but is intended to incorporate a laser? *	No
---	----

If the product as introduced into commerce does not incorporate a laser, identify the manufacturer and models of the laser that you recommend:

Item	No Information Provided.
------	--------------------------

Is it a product that is intended to be used with a laser? *	No
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If the product as introduced into commerce is intended to be used with a laser, identify the

manufacturer and models of the laser that you recommend:

Item	No Information Provided.
------	--------------------------

If your product does not incorporate a laser or you do not recommend a specific laser for use with the reported product, state the specifications of the laser or laser system which may be incorporated in or used with your product. This would include wavelengths, power or energy levels, etc.

2.4 Modification of a Laser Product

<i>Note:</i>	<i>Modification involves any changes to the product that affect its classification, performance or labeling requirements (as required by the standard or an approved variance).</i>
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Is your laser product the result of the modification of a laser product certified by another* manufacturer?	No
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2.5 Incorporation of Unmodified, Certified Laser Product

Does your laser product incorporate an unmodified, certified laser product?	*	No
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2.6 Incorporation of Uncertified Laser Product

Does your laser product incorporate an uncertified laser product as a component or component subsystem?	*	Yes
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2.6.1 Other Manufacturers

Item: 1

Give the name and address and/or firm establishment registration number of the other manufacturer: *

Laser tube manufacturer: SPT LASER TECHNOLOGY CO., LTD
 address: No.1, First Floor, Communication Technology Building, Wanda Road, Wanjiang District, Dongguan City, China
 alternative laser tube: Iradion's Laser
 laser pointer manufacturer:
 Guangzhou Sulei Laser Technology Co., Ltd
 ShenZhen XinKunYang Technology Co., Ltd

Identify the other manufacturer's model(s) and brand name(s): *

Item 1	CO2 LASER TUBE
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Item 2	SU6510-FP12
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Item 3	I80F
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Item 4	D650N1-G1230
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Provide the other manufacturer's accession number, if known: *	none.
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Show how your model designations and brand names correspond with the other brand names* and model designations listed:

The laser tubes made by the aboved mentioned manufacturer, from 40W to 150W, will be assembled for the laser cutter & laser engraver. class 2 position laser pointer (model: SU6510-FP12 or D650N1-G1230) will be assembled all the models.

2.7 Incorporation of Removable Laser System

Does your laser product incorporate a removable laser system or systems as defined by * 21 CFR 1040.10(c)(2)?	No
--	----

Technical Data

PART 3: DESCRIPTION OF THE PRODUCT

<i>Note:</i>	<i>In this section, you are asked to provide descriptions of the product, its intended function, and the laser radiation fields or paths and collateral radiation that may be accessible in operation, maintenance, or service modes of the product. This section was previously Part 5 of the product reporting guide.</i>
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3.1 Product Description and Function

<i>Note:</i>	<i>You may refer to brochures and manuals submitted as attachments to this report.</i>
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Describe the product and its function:

*

File Attachment	attachment 3.1 user manual 250927
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Details	Please refer to the user's manual, the product is a CO2 laser cutter & laser engraver.
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3.2 External and Internal Laser Radiation Fields and Paths

<i>Note:</i>	<i>Include beam path diagrams indicating protective housing, beam attenuators, viewports, scanners, targets, etc. Indicate energy and power levels at locations inside and outside the product.</i>
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Describe the external and internal laser radiation fields and paths: *	
Refer to the attached file. inside the protective housing of the laser cutting system, Class 4 CO2 laser radiation and 1mW pilot laser beam exist and thanks for the interlocked protective housing, during operation, no laser radiation is accessible.	
File Attachment	attachment 3.2 laser path diagram 250927

3.3 Operational Procedures and Accessible Radiation

<i>Note:</i>	<i>Describe here the procedures used during operation and the laser or collateral radiation that is accessible during these procedures.</i>
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List the procedures performed during operation: *
Inside the protective housing of the laser cutting system, Class 4 CO2 laser radiation and 1mW pilot laser beam exist and thanks for the interlocked protective housing, during operation, no laser radiation is accessible.

Do these procedures provide human access to ANY laser or collateral radiation? *	No
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Do the levels of laser or collateral radiation exceed the limits of Class I or Table VI?
--

Indicate those collateral and laser radiation fields to which human access is possible during those operation procedures. Include the locations and identifications of laser and collateral radiation

made accessible by viewing optics, viewports, and display screens:

3.4 Maintenance Procedures and Accessible Radiation

Note:

Describe here the procedures used during maintenance and the laser or collateral radiation that is accessible during these procedures.

List the procedures performed during maintenance:

*

During maintenance or adjusting, when the laser is started, the removeable door is opened, if the safety interlock switches are defeated, Class 4/ IV laser 10.6 um radiation is accessible. So the maintenance should be performed by a qualified and trained person only. during maintenance (adjusting), the position laser pointer will emit class 2/ II 650nm red laser radiation.

Do these procedures provide human access to laser or collateral radiation levels in excess of Class I or Table VI?

*

Yes

Indicate those collateral and laser radiation fields to which human access is possible during those maintenance procedures:

*

During adjusting the laser beam, when the door is opened and the safety interlock switches are defeated, Class 4/IV 10.6um laser radiation and/or Class 2/II 650nm laser radiation will be accessible. So the procedure should be performed by a qualified person only.

3.5 Service Procedures and Accessible Radiation

<i>Note:</i>	<i>Describe here the procedures used during service and the laser or collateral radiation that is accessible during these procedures.</i>
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List the procedures performed during service:	*
Refer to the service manual information, all the service should be conducted by a qualified person, during service, Class 4 10.6um invisible laser radiation and 650nm red laser radiation is accessible.	

Do these procedures provide human access to laser or collateral radiation levels in excess of Class I or Table VI?	*	Yes
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Indicate those collateral and laser radiation fields to which human access is possible during those service procedures:	*
Refer to the service manual information, all the service should be conducted by a qualified person, during service, Class 4 10.6um invisible laser radiation and 650nm red laser radiation is accessible.	

PART 4: CERTIFICATION, CLASSIFICATION, AND LEVELS OF RADIATION

<i>Note:</i>	<i>This section, covers the description of the certification and identification labels and the detailed explanation of your classification of the product.</i>
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4.1 Performance Standard Identification

With which performance standard does your product comply?	*	Federal Laser Product Performance Standard
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4.2 Certification Label

<i>Note:</i>	<i>Required by the CDRH standard and Laser Notice #50 for all laser products regardless of whether the CDRH laser standard or the IEC laser standard is being used for other requirements..</i>
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Is a certification label present on your product?	*	Yes
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Does your certification label state that the product complies with the FDA performance standards except for deviations pursuant to Laser Notice #50, dated July 24, 2007?	No
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Attach a copy of the certification label with an indication of its location on the product:	*
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refer to the attachment 4.

File Attachment	attachment 4 label and its location description 250927
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4.3 Identification Label

<i>Note:</i>	<i>Required on all laser products.</i>
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Attach a copy of the identification label with an indication of its location on the product:
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refer to the attachment.

File Attachment	attachment 4 label and its location description 250927
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4.4 Performance Standard Classification

Under which laser product performance standard are you classifying your product?	*	IEC 60825-1
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4.5 Laser Product Class

Indicate the Class of the Laser Product:	*	Class 1
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4.6 Operation

<i>Note:</i>	<i>For classification purposes describe the radiation levels accessible in any of the operational configurations of the product.</i>
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4.7 Embedded Laser System

<i>Note:</i>	<i>Describe here laser radiation fields contained within the protective housing of the product which may exceed the class of the product. The classification of the contained laser radiation is pertinent to safety interlock and protective housing label requirements.</i>
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4.7.1 Internal Radiation Levels

Does the protective housing contain radiation in excess of the Class of the product (such*	Yes
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as in a product that has a higher class laser embedded inside, such as a laser printer or workstation)?	
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4.7.2 Classification of Embedded Laser Radiation

Give the classification of laser radiation contained by the protective housing:	*	Class 4
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4.7.3 Radiation Parameters

Item: 1

Give specifications of laser radiation fields contained by the protective housing (please provide as much of the following as is appropriate to your product).

Identify which laser is being described.	*	CO2 laser-N30A
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Primary lasing medium or laser type	*	Carbon Dioxide
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If other, then please specify:	
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Primary wavelength (nm):	*	10600
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Maximum average radiant power (W):	*	447E-1
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Beam divergence, if symmetric:	*	7.5 mrad
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Beam divergence, if asymmetric (horizontal/vertical):	
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Beam diameter at laser aperture (mm):	*	18E-1
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Is the laser output pulsed?	*	No
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Pulse energy (J):	
Peak power (W):	
Pulse duration (sec):	
Repetition rate (Hz):	
Maximum irradiance (W/cm ²):	
Maximum radiant exposure (J/cm ²):	
Maximum radiance (W/cm ² sr):	
Maximum integrated radiance (J/cm ² sr):	

4.7.4 Other Radiation Fields

Are there other radiation fields to be described?

*

No

Please describe other radiation fields:

4.7.5 Basis of Reported Values

The values reported for the laser product are based *
on:

Measurements

Provide a diagram of your measurement set-up or the analysis used in your calculations. *

Provide pertinent dimensions such as separation distances, source and detector aperture size,

etc. to show compliance with the standard under which you are classifying:

please refer to the laser tube test procedure guidance document

File Attachment	attachment 4.7 laser radiation inspection guidance 250927
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4.8 Maintenance

<i>Note:</i>	<i>Describe here the laser radiation fields accessible in maintenance configurations of the laser product.</i>
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4.8.1 Radiation Class during Maintenance

Indicate the Class of the laser radiation accessible during maintenance:	*	Class 4
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4.8.2 Radiation Parameters

Item: 1

Give specifications of laser radiation fields to which human access is possible during maintenance (please provide as much of the following as is appropriate to your product).

Identify which laser is being described.	*	CO2 laser-N30A
Primary lasing medium or laser type	*	Carbon Dioxide
If other, then please specify:		
Primary wavelength (nm):	*	10600

Maximum average radiant power (W):	*	447E-1
Beam divergence, if symmetric:	*	7.5mrad
Beam divergence, if asymmetric (horizontal/vertical and units [rad deg])		
Beam diameter at laser aperture (mm):	*	18E-1
Is the laser output pulsed?	*	No
Pulse energy (J):		
Peak power (W):		
Pulse duration (sec):		
Repetition rate (Hz):		
Maximum irradiance (W/cm ²):		
Maximum radiant exposure (J/cm ²):		
Maximum radiance (W/cm ² sr):		
Maximum integrated radiance (J/cm ² sr):		

4.8.3 Basis of Reported Values

The values reported for the laser product are based on:	* Measurements
---	----------------

Provide a diagram of your measurement set-up or the analysis used in your calculations. *

Provide pertinent dimensions such as separation distances, source and detector aperture size, etc. to show compliance with the standard under which you are classifying:

File Attachment	attachment 4.7 laser radiation inspection guidance 250927
the values is same with clause 4.7, it bases on the measurement and calculation.	

4.9 Service

Note:	<i>Describe here the laser radiation fields accessible in service configurations of the laser product.</i>
-------	--

4.9.1 Radiation Class during Service

Indicate the Class of the laser radiation accessible during service:	*	Class 4
--	---	---------

4.9.2 Radiation Parameters

Item: 1

Give specifications of laser radiation fieldsto which human access is possible during service (please provide as much of the following as is appropriate to your product).

Identify which laser is being described.	*	CO2 Laser-N30A
Primary lasing medium or laser type	*	Carbon Dioxide
If other, then please specify:		
Primary wavelength (nm):	*	10600
Maximum average radiant power (W):	*	447E-1

Beam divergence, if symmetric:	*	7.5 mrad
Beam divergence, if asymmetric (horizontal/vertical):		
Beam diameter at laser aperture (mm):	*	18E-1
Is the laser output pulsed?	*	No
Pulse energy (J):		
Peak power (W):		
Pulse duration (sec):		
Repetition rate (Hz):		
Maximum irradiance (W/cm ²):		
Maximum radiant exposure (J/cm ²):		
Maximum radiance (W/cm ² sr):		
Maximum integrated radiance (J/cm ² sr):		

4.9.3 Basis of Reported Values

The values reported for the laser product are based * on:	Measurements
--	--------------

Provide a diagram of your measurement set-up or the analysis used in your calculations. *

Provide pertinent dimensions such as separation distances, source and detector aperture size, etc. to show compliance with the standard under which you are classifying:

basis of reported values is base on the measurement and calculation.

File Attachment	attachment 4.7 laser radiation inspection guidance 250927
-----------------	---

4.10 Collateral Radiation

Describe all collateral radiation fields associated with the product. Report the source(s) and levels and describe where and under what circumstances such radiation is accessible: *

No collateral radiation observed.

Provide a diagram of your measurement set-up or the analysis used in your calculations. *
Provide pertinent dimensions such as separation distances, source and detector aperture size, etc. to show compliance with the standard under which you are classifying:

No other collateral radiation observed.

PART 5: COMPLIANCE WITH PERFORMANCE REQUIREMENTS

Note: In this section, you will describe how your product complies with the performance requirements. This section was previously Part 7 of the product reports.

5.1 Protective Housing

Note: Required for all classes of laser products (see 1040.10(f)(1) and Compliance Guide).

Describe the product's protective housing and how it serves to prevent unnecessary human access to levels of laser radiation in excess of Class I: *

The laser beams (650nm and 10.6um) are enclosed in the housing of the product, the front door is inter-locked and when it open, the 10600nm and 650nm laser radiation will be shut off.

File Attachment	attachment 3.2 laser path diagram 250927
-----------------	--

Describe how the protective housing prevents access to unnecessary collateral radiation in excess of Table VI: *

No other collateral radiation for this 10600nm CO2 laser and 650nm diode laser.

5.2 Safety Interlocks

<i>Note:</i>	<i>Applicable for all Classes of laser products (see 1040.10(f)(2)(i) and Compliance Guide).</i>
--------------	--

Does your product have portions of the protective housing that are intended to be opened or removed for:

Operation:	Yes
------------	-----

Maintenance:	Yes
--------------	-----

Service:	Yes
----------	-----

Does your laser product incorporate any safety interlocks?	Yes
--	-----

What types of interlocks (select all that apply): *

Item 1	Magnetic Reed Switch
--------	----------------------

If other, then please specify:

Provide an electrical block diagram illustrating the logic of all interlock systems: *

refer to the attached file

File Attachment

[attachment 5.2 illustrating the logic of interlock system 250927](#)

Provide a detailed mechanical diagram showing where they all are located on the product: *

refer to the attached file

File Attachment

[attachment 5.2 illustrating the logic of interlock system 250927](#)

5.2.1 Safety Interlock Types

What type of safety interlock is this?

Defeatable

Is this interlock optional, as opposed to required under 21 CFR 1040.10(f)(2)?

No

See Laser Notice 17 for policy on optional interlocks at [Optional Interlocks - Labeling \(Laser Notice 17\) \(PDF Only\) \(PDF - 96KB\)](#)

Non-Defeatable Safety Interlocks

With which laser product performance standard does this type comply?

Select how this type operates:	
If other, please explain how it operates:	

Is this type designed to allow defeat?	
--	--

Actuated during:	
Item	No Information Provided.

To what radiation level does this type prevent access?

Defeatable Safety Interlocks

<i>Note:</i>	<i>Applicable to all laser products (see 1040.10(f)(2)(ii) and (iii)and ComplianceGuide).</i>
--------------	---

How does each interlock preclude replacement of the housing while that interlock is defeated?
Two interlock switches are designed for each removeable door (or window), and the two switches are series connected, if one of them is fail or defeated, the other will continue keep the interlock system in normal condition.

Describe the means of providing a visible or audible indication of defeat:
When the interlock switch is failed or when the door is opened, the control PC will show the information: the door is opening.

Fail Safe or Redundant Safety Interlocks

<i>Note:</i>	<i>Applicable to all required safety interlocks that prevent access to Class IIIb or IV (IEC: 3b and 4) levels of laser radiation. (see 1040.10(f)(2)(iii)).</i>
--------------	--

Describe how each safety interlock is "fail-safe," (i.e., precludes removal or displacement of the interlocked portion of the protective housing upon failure of the safety interlock or is redundant):

Describe the possible modes of failure of each safety interlock and the resultant effect upon the radiation safety of the laser product:

State the rating of each safety interlock, including the number of operational cycles before failure:

5.3 Remote Interlock Connector

<i>Note:</i>	<i>Applicable to Class IIIb or IV (and IEC:3B and 4) laser systems (see 1040.10(f)(3) and Compliance Guide).</i>
--------------	--

Does the product have a remote interlock connector that disables the* laser radiation when the circuit is open?
--

Not Applicable

Describe the electrical and mechanical construction and operation of the remote connector (give its circuit and physical location):

Record the open-circuit electrical potential difference between the terminals of the remote interlock connector:

5.4 Security Master (Key) Control

Note: Required for Class IIIb or IV (and IEC:3B or 4) laser systems (see 1040.10(f)(4) and Compliance Guide).

Does your product have a Security Master control?	*	Not Applicable
---	---	----------------

What type of security control is it?

If other, then please specify:

Describe how it works, including how the key control prevents unauthorized use of the product:

Is the key control removable in the "On" position?

Describe the function of the key control and how it renders the laser inoperable when the "key" is removed:

5.5 Laser Radiation Emission Indicator

Note: Required for Class II, IIIa, IIIb, or IV (and IEC: 3R, 3B, and 4) laser systems (see 1040.10(f)(5) and Compliance Guide).

Does the product incorporate any emission indicators?	*	Yes
---	---	-----

Describe in detail the mechanical and electrical characteristics of all emission indicators installed pursuant to Section 1040.10(f)(5)(i) or (ii) and give their locations:	*
--	---

an indication light is designed for this laser machine.

What type of emission indicator is incorporated?	*	Emitted Visible Beam
--	---	----------------------

If "other", please describe:

How is your emission indicator warning fail-safe or redundant?
--

5.5.1 Separation of Laser and Operation Control

Are the laser head, laser energy source or operation controller(s)	*	Not Applicable
--	---	----------------

separable by more than 2 meters?

Does the laser head and each control have an emission indicator?

5.5.2 Emission Delay

Note:

Required for Class IIIb and IV (and IEC: 3B and 4) (see 1040.10(f)(5)(ii) and Compliance Guide).

Is there a specific delay between the indication of emission and the actual emission? *

No

How is emission delay achieved?

If other, then please explain further:

Please provide additional information, as needed:

How many seconds is the emission indicator actuated prior to laser emission?

5.5.3 Emission Indicator Visibility through Protective Eyewear

Note:	<i>Applicable to Class II, IIIa, IIIb or IV (and IEC: 3R, 3B, and 4) laser systems [1040.10(f)(5)(iv)].</i>
-------	---

Is protective eyewear supplied with the laser system?	*	Yes
---	---	-----

Is protective eyewear recommended?	
------------------------------------	--

Can all visible emission indicators be seen through eyewear?	
--	--

5.6 Beam Attenuator

Note:	<i>Required for Class II, IIIa, IIIb or IV (and IEC: 3B or 4) laser systems (see 1040.10(f)(6) and Compliance Guide).</i>
-------	---

Note:	<i>You may be able to use currently approved alternate means or you may need to apply for approval of alternate means of providing this protection if this alternate means provides protection equivalent to a beam attenuator.</i>
-------	---

Does your product have a beam attenuator?	*	Not Applicable
---	---	----------------

Does your product have an alternative?	
--	--

Describe or attach request for approval of alternate means:

5.7 Location of Controls

<i>Note:</i>	<i>Applicable to Class II, IIIa, IIIb or IV laser products (see 1040.10(f)(7) and Compliance Guide).</i>
--------------	--

Are operational and adjustment controls located so that exposure to laser radiation, above the accessible emission limits of Class I and Table VI, is unnecessary?	*	No
--	---	----

Describe:

5.8 Viewing Optics

<i>Note:</i>	<i>Applicable to all laser products (see 1040.10(f)(8) and Compliance Guide).</i>
--------------	---

Does the product incorporate any of the following viewing optics:	*	Viewports
---	---	-----------

If so, please further describe the viewing optic that is incorporated:

a removable top cover is designed for the laser machine, the cover need to be opened during input or out put the processed material, and the top cover is safety interlocked.

Is the laser and collateral radiation that is accessible by virtue of viewing optics, viewports, or display screens less than the accessible emission limits of Class I and Table VI during operation and maintenance?	Yes
--	-----

Provide calculations and/or measurements, including pertinent attenuation factors, window transmission characteristics, etc.:

The window is made of tempered glass, and it can limit the CO₂ laser radiation less than the AEL of Class I during operation and maintenance.

File Attachment [attachment 5.8 view port description 250927](#)

5.8.1 Attenuation of Viewing Optics

Do the viewing optics, viewports, or display screen incorporate a shutter or variable attenuator?

Describe in detail, using diagrams or photographs and radiation transmission or reflection spectra, each shutter or variable attenuator incorporated into viewing optics, viewport, or display screen:

Describe how exposure of the eye to laser or collateral radiation in excess of the accessible emission limits of Class I (or IEC: 1M) and Table VI is prevented, for the following:

In the event of failure of the shutter or variable attenuator, as required by Section 1040.10(f)(8)(ii):

Whenever the shutter is opened or the attenuator is varied:

5.9 Scanning Safeguard

Note:	<i>Required for certain laser products with scanned laser radiation (see 1040.10(f)(9) and Compliance Guide).</i>
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Note:	<i>A safeguard is required when scan failure would cause the product to exceed the emission limits of its class.</i>
-------	--

Does the product incorporate a scanning safeguard?	*	Not Applicable
--	---	----------------

Describe the mechanical, electrical, and functional characteristics of any required scan failure safeguard:

Is the classification of the product based on the level of scanned radiation?	Not Applicable
---	----------------

What is the reaction time?	
----------------------------	--

Provide calculations to show that the safeguard's reaction time is adequate to prevent human access to laser radiation in excess of the product's class:

5.10 Manual Reset

Note:	<i>Applicable to Class IV laser systems manufactured after August 20, 1986. (see 1040.10(f)(10) and Compliance Guide).</i>
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Does the product incorporate a manual reset mechanism or means that prevents automatic restart following interruption of emission caused by power failure of at least 5 seconds or deactivation through the remote interlock connector? *	Yes
---	-----

Provide the circuit and physical description and location of the manual reset mechanism: *	
When the machine is interrupted by power failure or other unnormal operation, only manually restart can active the machine.	

Does emission delay reactivate when power is resumed after an interruption of 5 seconds* or more?	Yes
---	-----

Must the emission be manually restarted following interruption via the remote interlock connector? *	No
--	----

5.11 Medical Laser Product

<i>Note:</i>	<i>Applicable to Class III or IV (and IEC: 3B or 4) medical laser products intended for in-vivo surgical, therapeutic, or diagnostic irradiation of the human body (see 1040.11(a) and Compliance Guide).</i>
--------------	---

<i>Note:</i>	<i>The requirement in section 1040.11(a) does not apply to visible aiming beams less than the accessible emission limits of Class IIIa except for ophthalmic indications.</i>
--------------	---

Describe the means incorporated into the product to measure the level of laser radiation intended for irradiating the human body; include circuit diagrams and/or optical system diagrams:	
--	--

No medical laser product.

5.11.1 Laser Radiation Levels

Is the radiation level continuously monitored?

Explain how the radiation level is monitored:

Describe how the system can assure the accuracy of the displayed value to within 20%:

5.11.2 Measurement and Monitoring Uncertainties

Specify the uncertainty in the measurement system and describe the method by which it was derived:

Specify the uncertainty in the monitoring system and describe the method by which it was derived:

Describe how the displayed power/energy level is either measured at the point of delivery or measured earlier and then the actual output calculated:

--

If the displayed level is calculated, then provide calculations incorporating system constants, losses, attenuation factors, etc. to demonstrate accurate calibration of the delivered beam to +/-20%:

--

5.11.3 Calibration Procedures

<i>Note:</i>	<i>A procedure for calibration of the means for output measurement is required by the CDRH laser standard. However, if your medical laser product complies with IEC 60601-2-22 and you prefer to certify following Laser Notice #50, the IEC standard requires instructions for a calibration verification of the output beam.</i>
--------------	--

Are procedures and a schedule for recalibration of the measurement system included in the user instructions? If you are using the IEC 60601-2-22 standard for medical laser products in accordance with Laser Notice 50, do you provide instructions for doing a calibration verification of the output beam?

Identify location in the user instructions:

--

5.12 Surveying, Leveling, or Alignment Laser Products

<i>Note:</i>	<i>As a surveying, leveling, or alignment laser product it is subject to the requirements of section 1040.11(b).</i>
--------------	--

<i>Note:</i>	<i>If the product's class exceeds CDRH Class IIIa or IEC Class 3R or is IEC Class 1M or 2M, then an approved variance from the performance requirements in this section would be necessary prior to introduction into commerce.</i>
--------------	---

Is a variance request being submitted with this report?

5.13 Demonstration Laser Products

<i>Note:</i>	<i>As a demonstration laser product it is subject to the requirements of section 1040.11(c).</i>
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<i>Note:</i>	<i>If the product's class exceeds CDRH Class IIIa or IEC Class 3R or is IEC Class 1M or 2M, then an approved variance from the performance requirements in this section would be necessary prior to introduction into commerce.</i>
--------------	---

<i>Note:</i>	<i>An Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device (form FDA 3147) must be submitted, following the instructions on the form. A Laser Light Show Report may also be required for Class IIIb or IV shows or displays.</i>
--------------	--

<i>Note:</i>	<i>You may prepare all these reports and the variance request together using eSubmitter and transfer them all to a single CD to ship to CDRH, if that's the preferred method of submitting. If you do this you need to remember that during packaging of each submission you must print and sign each submittal letter, then send each letter (either scanned & attached following the packaging instructions or just inserted into the envelope with the CD).</i>
--------------	--

Is a Laser Light Show report being submitted along with this report?	
Is a variance application for a laser light show projector and laser light show being submitted along with this report?	
Does its user instructions include a warning not to direct the laser radiation at the audience?	

PART 6: COMPLIANCE WITH LABELING REQUIREMENTS

<i>Note:</i>	<i>In this section, you will describe how your product complies with the labeling requirements. This section was previously Part 3 of the product reporting guide.</i>
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<i>Note:</i>	<i>For each of the following labels required for the product being reported, provide a sample or a facsimile of each label. Clearly indicate the locations on the product of all required labels. Submitting diagrams, photographs, blueprints, product literature, etc. is acceptable (see laser notices # 16, 17, 45, and 50).</i>
--------------	--

6.1 Performance Standard Identification

With which performance standard do your product's labels comply:	* Federal Laser Product Performance Standard
--	--

6.2 Warning Logotype Label

<i>Note:</i>	<i>Required on Class II, III, and IV laser products. (see 1040.10(g)(1), (2),(3),(4),(8),(9),(10) and Compliance Guide).</i>
--------------	--

Attach a copy with an indication of its location on the product:

*

see the attached document.

File Attachment

[attachment 4 label and its location description 250927](#)

6.3 IEC Warning Label

Note:

Required on all Class 1, 1M, 2, 2M, 3R, 3B, and 4 laser products.

Attach copies of both the warning label (hazard symbol) and the explanatory label with an indication of their locations on the product. If the radiation output and the standard used are not stated on the explanatory label, then a copy of the label giving this information and its location on the product must also be attached.

File Attachment

[attachment 4 label and its location description 250927](#)

6.4 Class IIa Warning Label

Note:

Required on Class IIa laser products (see 1040.10(g)(1)(i) and Compliance Guide).

Attach a copy with an indication of its location on the product:

6.5 Aperture Label

<i>Note:</i>	<i>Required on Class II, III and IV (IEC: 3R, 3B, and 4) laser products (for nonmedical laser products see 1040.10(g)(5),(8),(9),(10) or for medical laser products see 1040.11(a)(3) and Compliance Guide).</i>
--------------	--

Attach a copy with an indication of its location on the product:

refer to the attachment.

File Attachment	attachment 4 label and its location description 250927
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6.6 Protective Housing Labels

<i>Note:</i>	<i>See 1040.10(g)(6),(7),(8),(9),(10), Compliance Guide, and Laser Notice 17.</i>
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Does your product have any protective housing labels?	*	Yes
---	---	-----

Does your product have any noninterlocked protective housing labels?	*	Yes
--	---	-----

Attach a copy with an indication of its location on the product:	*
--	---

refer to the attached file.

File Attachment	attachment 4 label and its location description 250927
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Indicate how the label(s) are visible both prior to and during opening or removal of housing:	*
---	---

refer to the attached file. the label is affixed on the edge near the protective housing.

Does your product have any defeatably interlocked protective	*	Yes
--	---	-----

housing labels?	
Attach a copy with an indication of its location on the product: *	
The removable cover (door) is interlocked, and the label is affixed on the edge of the product near the interlock switches.	
File Attachment	attachment 4 label and its location description 250927
Indicate how the label(s) are visible both prior to and during interlock defeat: *	
Because the label is affixed on the product surface, not on the moveable doors, so even the door is opened or removed, the label is still visible.	

Does your product have any optionally interlocked protective housing* labels?	No
Attach a copy with an indication of its location on the product:	
Indicate how the labels are visible both prior to and during opening or removal of the housing:	

PART 7: COMPLIANCE WITH INFORMATIONAL REQUIREMENTS

<i>Note:</i>	<i>In this section, you will describe how your product complies with the informational requirements. This section was previously Part 4 of the product reporting guide.</i>
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7.1 User Information

Submit a copy of user information (operator's manuals) for your laser product. If the manual is* very extensive, submit those portions that confirm compliance with Section 1040.10(h) [and 1040.11(a)(2), if a medical laser product]:

See the attached file.

File Attachment	attachment 3.1 user manual 250927
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Does the manual contain adequate instructions for assembly, operation, and maintenance?	*	Yes
Does it contain clear warnings to avoid exposure?	*	Yes
Does it contain a statement of output parameters?	*	Yes
Does it contain legible reproductions of all labels, their locations on the product, and hazard warnings?	*	Yes
Does it contain a listing of controls, adjustments, and procedures for operation and maintenance?	*	Yes
Does it contain a schedule of maintenance?	*	Yes
Does it contain the "Caution - use of controls..." warning statement?	*	Yes
Does it include information to determine nominal hazard zone for users?	*	Yes
Does it contain a compatibility statement concerning recommended lasers or specifications?	*	Not Applicable
Does it contain an additional warning stating that viewing the laser output with optical instruments may result in an eye hazard for Class 1M or an increased hazard for Class 2M?	*	Not Applicable

Note:	<i>These materials may also have been used in the product description required by Part</i>
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	3.
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7.2 Promotional Literature

Submit copies of any sales literature, including catalogs, specification sheets, and descriptive * brochures for Class IIa, II, III, and IV laser products:

No such promotional literature for this product.

<i>Note:</i>	<i>This material is needed to demonstrate compliance with Section 1040.10(h)(2), which states that a reproduction of the warning logotype is required in all catalogs, specification sheets, and descriptive brochures.</i>
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7.3 Servicing Information

Submit a copy of the relevant radiation safety sections of your product's servicing information * (from your service manual):

refer to the attachment.

File Attachment	attachment 7.3 safety rules 250927
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Quality Control

PART 8: PRODUCT DESIGN VERIFICATION

<i>Note:</i>	<i>In this section, any attached files must identify the manufacturing facility and name of the responsible Quality Assurance manager for the activity. This section was previously Part 9 of the laser product reporting guide.</i>
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	<i>In this section, you will also describe those design considerations, verification activities, and controls implemented to ensure that the reported product will remain in compliance with the Federal laser product performance standard during its useful life.</i> <i>Quality control and product testing should be based on design considerations and factors that can affect product compliance with the Federal laser product performance standard.</i>
--	---

8.1 Critical Design Requirements

List the factors identified during design that may provide product compliance with the Federal* laser product performance standard or performance as related to accessible or emitted laser radiation (e.g. performance specifications, component selection):

The product is a class 1 laser product, during operation, class4/IV CO2 laser radiation and 650nm 1mW pilot laser beam are enclosed by the interlocked protective housing.

File Attachment	attachment 8.1 laser specification 250927
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8.2 Life Testing

<i>Note:</i>	<i>In this section you will describe those verification activities conducted to assure product compliance with the Federal laser product performance standard over its useful life.</i>
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<i>Note:</i>	<i>Maintenance and/or service instructions must include schedules for maintenance and replacement of components that may be necessary for the compliance of the product during its useful life.</i>
--------------	---

Testing of features designed to meet Federal laser product performance requirements:	*
--	---

A protective housing is designed for this laser machine, the top cover (door) can be opened, a couple of interlock switches are designed for the cover. the product is designed as a Class 1 laser product.

Acceptance of electrical and electronic components:	*
---	---

IQC will inspect the critical components, make sure they are accord with their specification.

File Attachment	attachment 4.7 laser radiation inspection guidance 250927
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Dimensional stability and rigidity of mechanical parts and assemblies such as housings and mounts:	*
--	---

All of the brackets and housing are of metal, and they are strong enough to resist normal operation in its useful life.

Environmental stability of components such as filter materials, coatings, and adhesives:	*
--	---

There is no filter materials, coatings or adhesives used for the product, no further environmental stability assessment is performed.

Other factors that might affect your product's radiation safety:

Provide an estimate of the useful life of the product (in years):	*	20
---	---	----

8.3 Change Controls

Describe the controls implemented to assure compliance with the Federal laser product performance standard (e.g. control of design changes, user and service information changes, labeling changes to assure that compliance of the product is not jeopardized.): *

If there is any change to the laser cutting machine, We will send a supplement report to FDA, CDRH.

PART 9: QUALITY CONTROL TESTS AND PROCEDURES

Note: In this section, any attached files must identify the manufacturing facility and name of the responsible Quality Assurance manager for the activity. This section was previously Part 8 of the laser product reporting guide.

Section 1010.2(c) requires that certification be based on a test, in accordance with the standard, of each unit or on a program in accordance with good manufacturing practices.

Failure to maintain an adequate testing program may result in disapproval of the program by CDRH.

9.1 Quality Control Documentation

Note: Attach samples of documents that describe, specify, or relate to procedures or tests used to ensure compliance of your reported product with the standard, including compliance with all performance, labeling, and informational requirements.

Specification controls for critical components:

See the attached file for the CO2 laser tube inspection.

File Attachment [attachment 4.7 laser radiation inspection guidance 250927](#)

Manufacturing and assembly control procedures:

See the attachment 9.

File Attachment

[attachment 9 assembly manufacturing and inspection flow chart 250927](#)

Inspection and test control procedures:

See the attachment.

File Attachment

[attachment 9 assembly manufacturing and inspection flow chart 250927](#)

Assembly and test traveler forms:

Inspection and test reports and checklists:

refer to the attachment for the checklists.

File Attachment

[attachment 9.1 FQC inspection procedure guidance and records 250927](#)

Other(s), specify:

9.2 Alternate Quality Control Procedures

If formal quality control and testing procedures have not been implemented or are not sufficient to assure that your product(s) will comply with the standard, explain how you assure that your products comply and submit supporting documentation:

No other alternate quality control procedures.

PART 10: INSTRUMENTATION AND CALIBRATION

Note: In this section, you will describe the instrumentation used for compliance testing your product and the instrumentation calibration procedures.

10.1 Component Testing

Do you purchase components or services from contractors or original equipment manufacturers in lieu of conducting your own in-house testing?	*	Yes
Provide certificates or sample test/inspection records from suppliers or original equipment manufacturers, etc. to assure that those entities are operating in a state of control.		
IQC will full check the critical components, all the labels, structures and user's manual are designed according to the regulation CFR1040.10.		
File Attachment	attachment 4.7 laser radiation inspection guidance 250927	

Describe those tests and controls used to determine whether the reported product is produced to be in compliance with the Federal laser product performance standard:

The carbon dioxide laser tube belongs to a Class 4 laser product, thank for the interlocked protective housing of the laser machine, for the finished product, no laser radiation is accessible.

Do you conduct in-house compliance testing for your product?	Yes
--	-----

Do you have testing done by an outside contractor?

*

No

10.2 Compliance Testing

Describe those tests and controls used to determine whether the reported product is produced to be in compliance with the Federal laser product performance standard:

*

For this class 1 laser cutter system, we have designed a class1 protective housing, and the two safety interlock switches are designed for the removeable door during operation. we have affixed all required labels for this laser cutter. We assure this product is in compliance with the CFR standard.

List the instruments you use to determine compliance of the reported product with the standard. Describe these instruments or provide copies of specification sheets. Identify each detector's aperture size, if applicable.

*

File Attachment

[attachment 10.2 laser power meter specification 250927](#)

Refer to the attached file: user's manual for laser power meter.

Indicate how the measurement system collects or accounts for the total radiant energy or power specified in Section 1040.10(e):

*

Because the active absorb area of the laser power probe is large enough compare to the size of the laser beam under test, so is easy to detect the total radiation power of the laser.

File Attachment

[attachment 4.7 laser radiation inspection guidance 250927](#)

Provide a measurement error analysis (for all sources of error identified) and an uncertainty statement for all measurement data reported. (If it is clear from the measurement data, including the total estimated uncertainty, that the levels are well below the applicable class limit, then an error analysis and uncertainty statement are not required. For example, an error analysis and uncertainty

statement would not be required for a 1.5 milliwattHeNe laser product classified in Class IIIa.):

For inside laser radiation, laser power is obviously excess Class IIIb limitation, belongs to Class IV laser radiation. For the end product, thank for the interlocked protective housing, during operation, no laser radiation is accessible, the product is classified Class 1 laser product.

10.3 Calibration

Provide instrument calibration schedules and indicate how your instruments are calibrated *
(e.g.,calibrated by your company against a working standard, returned to the manufacturer of the instrument, sent to an independent calibration laboratory) [If your laser product operates at a level closely approaching a specified limit, high accuracy and traceability to the National Institute of Standards and Technology (previously known as the National Bureau of Standards) are important]:

The laser power meter will be sent to an independent calibration lab for calibration once a year.

File Attachment	attachment 10.3 laser power meter calibration report 250927
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Stop:	<i>You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.</i>
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