Section: eRadHealth Menu

Introduction

Electronic Product Radiation Safety Reporting Form

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This FDA Electronic Submission (eSub) software is the next version of the application developed to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

All electronic reports and correspondence can either be transferred to CD and mailed to the address below, or can be sent via the FDA Electronic Submissions Gateway to CDRH. If you follow instructions to set up an account with the FDA Gateway, it currently may take several weeks,, but when you submit through it you will receive your acknowledgement email message with Accession Number within minutes! Or, in the interest of faster turn-around for a one-time urgent report of if you submit few reports, you may simply fill out this template creating the submission and then at 'Packaging' follow the instructions to transfer the files to a CD to mail in. This method of submitting your report will be acknowledged by an email with the Accession Number within several days.

Information about the FDA Electronic Submissions Gateway can be found at **www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm**. Please contact the Gateway Helpdesk with your questions about that system.

Electronic submissions on CD should be mailed directly to the Document Control Center at:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions received in the mail on CD will be processed within a few days of receipt.

Note about eSubmitter software:

Instructions provided in this software briefly summarize the requirements of the regulations under the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control, that applies to manufacturers of electronic products that emit radiation. The software provides questions relevant to requirements in the performance standards and may include explanations or clarification about the performance, labeling, and informational requirements of the standard. It does not replace the regulations, however, and if there is any conflict between the software and the regulations, the regulations must prevail. Throughout this application, pertinent sections of Title 21, Code of Federal Regulations, Chapter I, Subchapter J, are cited in parentheses. Please consult them before making design or procedural decisions.

Regulatory requirements for radiological products can be found at **http://www.fda.gov/Radiation-EmittingProducts/default.htm** and for medical devices are located at **www.fda.gov/M/devaDvices/default.htm**. If you have specific questions about the regulations, please contact us at: **DSMICA@fda.hhs.gov**.

If you have specific questions regarding this software, please contact the eSub team by email at: **eSubmitter@fda.hhs.gov**.

Thank you for using our electronic product reporting software. Please communicate your comments and suggestions to the eSub team as often as you like.

Thank you for your continued support of the FDA Electronic Submission Program (eSub).

Definitions

Definitions for Rad Health Products

Manufacturers

Manufacturer is any person or organization engaged in the business of manufacturing, assembling, or importing of electronic products (21 CFR1000.3(n)). Manufacturers of electronic products subject to 21CFR1000-1050 must:

- Design and manufacture their products to be in compliance with applicable performance standards;
- Test their products to assure compliance;
- Certify compliance of their products;
- Maintain test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries;
- Use the published reporting forms or electronic software application to submit reports to CDRH, including Product reports describing the manner of compliance of the product design and testing program and Annual Reports summarizing their compliance testing;
- Report accidental radiation occurrences (i.e., possible, suspected,or known exposures);
- Report any radiation defects or noncompliances; and
- Recall (i.e., repair, replace, or refund the purchase price of) defective or noncompliant products.

Importers

Importer is any person of organization engaged in the business of importing electronic products. An importer is considered to be a manufacturer. The requirements for Manufacturers given above also apply to importers if the requirements have not been done by the foreign manufacturer.

United States Agent for Foreign Manufacturers

Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer`s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) of the Radiation Control for Health and Safety Act of 1968 (21U.S.C. 360mm(d)) and this section. The agent maybe an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

From The Federal Food, Drug, and Cosmetic ActSec 536 [21 U.S.C. 360mm](d)

Designation of agent for purposes of service

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It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

Sec. 531 [21 U.S.C. 360hh] (1) the term **''electronic product radiation''**means:
(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or
(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.
Sec. 531 [21 U.S.C. 360hh](2) the term **''electronic product''**means:
(A) any manufactured or assembled product which, when in operation,(i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or
(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effect

Role

What is your role?	[L]
Note:	If you are acting as an agent of the actual manufacturer, please select your role as, for example, perhaps an Importer or Consultant. Later in the report, under Manufacturer Data, you will be prompted to enter both manufacturer and submitter information.

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

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.) [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]	
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)

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. [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]
What Type of Product is this Radiation Safety Report about?
[L]
What Type of Product is this Annual Report about?
[L]
What Laser Light Show Document are you filing?
[L]
What Type of Correspondence is this?
[L]
What Type of Product is this Variance Request about?
[L]

FDA or State Inspector

Abbreviated Report Applicability

OEM Laser Applicability

Section: Manufacturer Data

General Information

General Information for Radiological Health Products

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH).

The Radiological Health staff, CDRH developed this software application for the Product and Annual reports. This application will assist manufacturers of electronic products that emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements 1,2,3.

Reports submitted on radiation safety of electronic products must follow the appropriate form (21 CFR 1002.7). This software application serves the same report responsibility, so long as the submitter or manufacturer prints out the cover letter and sends it in along with the CD containing the report files. The submitter of the report will receive an acknowledgment letter (or email message) with the accession number that CDRH assigns to the report. Please reference this accession number in the future when providing

additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database.

CDRH DOES NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce, 21 CFR 1002 requires the manufacturer to submit the product and Annual Reports and to comply with all applicable importation requirements (21CFR 1005). If there are deficiencies, CDRH may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. CDRH will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21CFR 1003 - 1004) for products already introduced into commerce.

CDRH can now accept and process 'CeSub' electronic submissions at this time, if all attachments are PDF files only, and the cover letter is printed out and included with a real signature. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy (save a copy to your hard drive) of the completed report in your records.

Regulatory information is available on the Internet under **www.fda.gov/Radiation-EmittingProducts/default.htm**. No copyright exists for these forms.

Reproduce these forms as needed. If you would like to comment on the reporting forms, website, or future electronic submissions, you may direct the comments to **cdrhesub@cdrh.fda.gov**.

A complete Product Report is required for each product model or model family. Product Reports are now more generally referred to as Radiation Safety Reports to distinguish the Radiological Health submissions from medical device submissions. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the form where there are differences to report, referencing the number of the affected item. Items that are unchanged will still appear in the supplement from the original report.

When new models of a product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports may be submitted using the Annual Report software included in this application. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.10(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

Burden to Industry

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Manufacturer and Report Information

Confirmation:	This Manufacturer section of this report requests names, addresses, phone numbers, etc. for your firm, various officials of your firm, consultants who may assist in preparing the report, parent firm (if any), importer and designated agent (for foreign firms). Some of this information is mandatory and its absence will prevent you from completing the report submission. Because some of these entries may be redundant, utilize the 'Contact Address Book' feature so you can save your data and reselect the entries later and in the future. (See the upload/download buttons in upper right corner of the screens). You can check for missing data at any time using the "Missing Data Report" from the "Output" menu across the top of this application. The Missing Data Report lists all missing responses that are required (that have the blue dot).

Information:	Attention: Variance Applicants If you are acting as an agent or consultant for, or on behalf of, or filing for, a company that will be manufacturing or producing a Class IIIb or IV projector or laser light show or both which require an approved variance, the following explanations may provide further clarification. Manufacturer: This is the firm or company who is requesting the variance, will certify the product or show, and will be the holder and owner of the variance. This is not the agent or consultant who may be filing this report or Variance request for the manufacturer; that agent may be the submitter, identified in a later screen. Responsible Individual: This person works for the Manufacturer and is responsible for compliance of the projector and/or show. In the case of laser light shows, he or she may be the company president, CEO, or the laser light show head operator or a manager who oversees the shows. Reporting Official: This person works for the Manufacturer and is responsible for reports, recordkeeping, and submitting FDA required documents and correspondence.

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: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]

Responsible Individual

Note:	The responsible individual is the highest level and most responsible individual affiliated with this establishment.

Select the Responsible Individual from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Manufacturer's Reporting Official

Note:	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 intesting and quality control procedures submitted to FDA must be signed by this individual.
Select the Reporting Official from Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	

Report Submitter

Note:	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 prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.
Select the Submitter from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	
Internal Reference Number:	

Parent Establishment

Is there a parent establishment?	[L]

Select the Parent Establishment and Contact from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Manufacturer Designated United States Agent

Note:	Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.

Is there a United States agent that has been designated by the manufacturer?	[L]

Written Agreement

Item: 1 (could contain up to 10 items with none required)

Note:	The manufacturer who is certifying the product being reported is the manufacturer of record. If this firm is not in the United States, please identify your current Importer(s).

Note:	If any of the required responses below do not apply to your designated agent, enter 'NOT APPLICABLE' or 'NA.'
Select the Designated Agent from the Contact Address book:	
Contact Name	
Occupation Title	

Email Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
Attach a copy of written agreement with the designated U.S. agent:	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Importer

Item: 1 (could contain up to 10 items with none required)

Select the Importer from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Additional Manufacturing Locations

Item: 1 (could contain up to 100 items with none required)

Note:	If any of the products certified in this report are manufactured at locations other than listed in the Manufacturer Responsiblefor 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.
Select the Manufacturer Address from the Establishment Address book: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]	
Code used on identification labels:	

Section: Product Data

Product and Model Identification

Attention - Information about this section

In this section you'll be asked to identify several required or optional things which will help FDA/CDRH staff to prioritize their reviews. You'll be asked to consider the following aspects:

(1) Identify your product's radiation type and the CDRH Product Code.

(2) Enter an Accession number if this will be a report supplment. If you are preparing a supplement, you'll see that after entering a valid 7-digit Accession number many questions will no longer be required (they will either be disabled or will be optional, meaning they will no longer have the blue dot).

(3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or

correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.
(4) If you find that you have more information that you want the FDA/CDRH to read but it doesn't seem to fit under other questions, we have a final "***Additional Information***" question in this section which invites you to add comments and/or attach a file that provides further information from your firm about this submission. This is the place to add that extra information.

Product Type Reported

Note:	Each product that CDRH regulates is assigned a product code by CDRH.

What is the product code?

To select the three letter product code,

- Click the plus sign. You will see a product code filter dialog box.
- Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose.
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code. [QUESTION TYPE NOT YET IMPLEMENTED: RH SINGLE PRODUCT CODE]

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?	[L]
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?	[L]
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?	[L]
If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.	

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)r" 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

Note:	Check all items in this section that may apply to this submission.

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 NOTE: There is no need to send a copy of the CD to Division of Dockets Management.

Noncompliances or Defects

Does this document or any of its attachments contain:	
A notification of noncompliance or defect?	[L]
You may provide an explanation and/or attach a document here:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Responses to Noncompliances or Defects

Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?	
A refutation of noncompliances or defects identified to your firm?	[L]
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)?	[L]
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production?	[L]
Note:	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 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."
A description of any design changes that correct noncompliances for future production?	[L]
Note:	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.
You may add an explanation and/or attach a document here:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Details	[HTML Text]

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)?	[L]
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)?	[L]
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)?	[L]
Request for approval of alternate labeling?	[L]
Application for alternate test procedures (21 CFR 1010.13)?	[L]
You may provide an explanation and/or attach any relevant documents here:	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Variance Requests

Information:	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.
Message:	Click the plus sign to list the requirements from which you are requesting a variance.
This submission includes an application for a variance from certain requirements.	
Item 1	
Item 2	
Item 3	
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Stop:	For all Variance requests, two submissions must be made to the FDA. 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: U.S. Food and Drug Administration Center for Devices and Radiological Health Attn: eSubmitter Team Document Mail Center - WO66-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

	Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to: Food and Drug Administration Division of Dockets Management (HFA-305) 5630 Fishers Lane, Room 1061 Rockville, MD 20857

Responses to Communications from FDA

Does this document or any of its attachments contain:	
A response to an FDA inspection?	[L]
What was the date of the inspection?	[Date]
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	[L]
What was the date of the Warning Letter or other notification letter?	[Date]
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)?	[L]
What was the date of the inquiry?	[Date]
A response to any other communication from FDA?	[L]
What was the date of the communication?	[Date]
Provide an explanation:	
[Multi-Line Plain Text]	

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	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Private Labeling

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

Private Labeling-Table

Item: 1 (could contain up to 20 items with 1 required)

Give the name and address of the manufacturer:	
Establishment Name	

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Division Name	
Email Address	
Address	
Telephone Number	
Fax Number	
Give the firm establishment registration number of the manufacturer listed above (if known):	

Enter brand names and/or model designations in the following table by clicking on the Add button. If you prefer to attach a file, please click on the Add button and enter the text "See File Attachment" as the first table entry.	
Item 1	
Item 2	
Item 3	
List of Brand Names and/or Model Designations	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

The Original Equipment Manufacturer (OEM) accession number (if known):	

Explain how the brand names and model designations correspond with your own brand names and model designations:
[Multi-Line Plain Text]

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.
[Multi-Line Plain Text]

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.
[Multi-Line Plain Text]

Note:	See also http://www.fda.gov/MedicalDevices/default.htm for more information on medical device premarket clearance procedures.

Section: Ultrasonic Therapy Product

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 have a model family or brand name, leave the field blank.

Model Designation (Names and/or Numbers):			
Item			
Item 1		Item 2	

Product Classification

Indicate below the type of product or family of products covered by this report.	
This report covers:	[L]
Is your system a continuous-wave (CW) unit or an amplitude-modulated (AM) unit?	[L]

Performance Specifications

Note:	The information reported in this section will be used to determine whether the product complies with the requirements set forth in 21 CFR 1050.10(c). Several items must be reported in terms of definitions that are provided by the standard; please refer to 21 CFR Part 1050.10 for these definitions.

Frequency of Operation

Note:	Provide the following data for operating frequency(ies) in MHz for either fixed, variable, or multiple frequency systems.
Fixed at _____ MHz:	
_____ MHz:	
Variable, from _____ MHz to _____ MHz:	
Minimum MHz:	
Maximum MHz:	
Multiple, fixed at _____ MHz, _____ MHz, and _____ MHz:	
_____ MHz:	
_____ MHz:	
_____ MHz:	
Operating frequency (ies) are indicated to the user by:	

Output Parameters for Continuous-Wave Units

Temporal-average ultrasonic power:	
Message:	Variable, from _____ Watts to _____ Watts:
Minimum Watts:	
Maximum Watts:	
Indicated to the user by:	

Temporal-average effective intensity:		
Message:	Variable, from _____ W/cm² to _____ W/cm²:	
Minimum W/cm²:		
Maximum W/cm²:		
Indicated to the user by:		

Output Parameters for Amplitude-Modulated Units

Temporal-maximum ultrasonic power:		
Message:	Variable, from _____ Watts to _____ Watts:	
Minimum Watts:		
Maximum Watts:		
Indicated to the user by:		
Temporal-maximum effective intensity:		
Message:	Variable, from _____ W/cm² to _____ W/cm²:	
Minimum W/cm²:		
Maximum W/cm²:		
Indicated to the user by:		
Output pulse width:		
Message:	Fixed at _____ milliseconds:	
_____ milliseconds:		
Message:	Variable from _____ milliseconds to _____ milliseconds:	
Minimum milliseconds:		
Maximum milliseconds:		
Indicated to the user by:		
Output pulse repetition rate:		
Message:	Fixed at _____ pulses/second:	
_____ pulses/second:		
Message:	Variable, from _____ to _____ pulses/second:	
Minimum pulses/second:		
Maximum pulses/second:		
Message:	User selected from the available settings (list available settings):	
Setting 1:		
Setting 2:		

Setting 3:	
Indicated to the user by:	

Timer Specifications

Timer accuracy for settings of:	
Less than 5 minutes:	
Provide the number of minutes: (+/- _____ minutes)	
Between 5 and 10 minutes:	
Provide the number of minutes as a percent: (+/- _____ percent)	
Greater than 10 minutes:	
Provide the number of minutes: (+/- _____ minutes)	

Maximum timer setting: (____ minutes)	
How does ultrasonic emission automatically terminate at the end of preset time?	
[HTML Text]	
How can ultrasonic emission be terminated prior to the end of the preset time?	
[HTML Text]	
How is radiation emission routinely terminated?	
[HTML Text]	

Applicators

Type of applicators:	
Collimating, with an effective radiating area (ERA) of _____ cm^2:	
Diverging, with an effective radiating area (ERA) of _____ cm^2:	
Focusing, with focal area of _____ cm^2 and a focal length of _____ cm:	
Transducer Configuration:	
Single Crystal (specify material):	
For multiple elements, describe each element, the manner in which connected, and the resulting effect on the radiated field.	
[HTML Text]	

Cables

How is application of electrical power to the transducer indicated to the user?
[HTML Text]
How is a broken cable or open connection indicated to the user?

[HTML Text]

Labeling Requirements

Note:	The information reported in this section will be used to determine whether the product complies with the requirements set forth in 21 CFR Parts 801, 1010.2, 1010.3 and 1050.10(d). Most of the items below require that a copy of the label be attached; if labels are unavailable at the time of reporting, please provide a specification control drawing.

Certification

Note:	Part 1010.2 of 21 CFR requires that the product (generator and applicator, if detachable) bear a permanently affixed tag or label certifying that it complies with the provisions of Part 1050.10. Provide the following information concerning the certification label:
The manner in which the label is attached:	
[HTML Text]	
The location of the label:	
[HTML Text]	
Attach a sample of the label.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Identification

Note:	Part 1010.3 of 21 CFR requires that the product (generator and applicator, if detachable) bear a permanently affixed tag or label giving the following information:(a) The name and address of the manufacturer. (Where the product is sold under a name other than that of the manufacturer, the name and address of the individual or company under whose name the product is sold may be given on the label, provided that such individual or company has previously supplied the CDRH with the name and address of the manufacturer.)(b) The place, month, and year of manufacture. (The place of manufacture may appear in coded form if the manufacturer has previously supplied the CDRH with the codes and their meaning). The month and year of manufacture must be given without abbreviation and with the year as a four-digit number (for example: Manufactured: September 1978.)
Message:	Provide the following information concerning the identification label:
The manner in which the label is attached:	
[HTML Text]	
The location of the label:	
[HTML Text]	
Attach a sample of the label.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Generator Labels

Note:	Part 1050.10(d)(3) of 21 CFR requires that each ultrasonic therapy generator bear a label giving the following information: (a) The brand name, model designation, and serial number of the generator. (b) The ultrasonic frequency (unless variable, and indicated on the controls). (c) The type of waveform (continuous wave or amplitude modulated). In addition to the above, generators employing amplitude modulated waveforms are required to bear additional labeling giving the following information: (a) Pulse duration and repetition rate (unless variable, and indicated on the controls). (b) An illustration of the waveform. (c) The ratio of the temporal-maximum effective intensity to the temporal-average effective intensity. If this ratio is a function of any operation control setting, then the range of the ratio shall be given, and the waveform illustration shall be for the maximum value of this ratio.
Message:	Provide the following information concerning the generator label:
The manner in which the label is attached:	
[HTML Text]	
The location of the label:	
[HTML Text]	
Attach a sample of the label.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Applicator Labels

Note:	Part 1050.10(d)(4) of 21 CFR requires that each ultrasonic therapy applicator bear a label giving the following information:(a) The brand name, model designation, and serial number of the applicator.(b) Thedesignation of the generator for which the applicator is intended.(c) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging), and, for focusing applicators, the focal length and focal area.
Message:	Provide the following information concerning the applicator label:
The manner in which the label is attached:	
[HTML Text]	
Attach a sample of the label.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Operation Controls

Note:	Part 1050.10(d)(1) of 21 CFR requires that each operation control be clearly labeled, identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, labeling the units of measure of that function is required for the indicator but not for the control.
Provide drawings, photographs, or other documents, which show clearly the location and labeling of all such controls. Click on the Add... button below to attach and select the files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Service Controls

Note:	Part 1050.10(d)(2) of 21 CFR requires that each service control that is accessible without displacement or removal of any part of the product be clearly labeled, identifying the function controlled and including the phrase for service adjustment only.
Provide drawings, photographs, or other documents, which show clearly the location and labeling of all such controls. Click on the Add... button below to attach and select the files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Information Requirements

Note:	Provide the following information regarding servicing information, user information, and product description.

Servicing Information

Note:	Part 1050.10(f) (1) of 21 CFR requires a manufacturer to provide to servicing dealers and distributors adequate instructions for operation, service, and calibration of the product. This must include:(a) A description of those controls and procedures that could be used to increase radiation emission levels.(b) A schedule of maintenance necessary to keep the product in compliance with 21 CFR 1050.10.(c) Any safety precautions that may be necessary regarding ultrasonic exposure.
Attach a copy of the servicing information clearly identified above. Click on the Add... button below to attach and select the files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

User Information

Note:	Part 1050.10(f)(2) of 21 CFR requires a manufacturer to provide users with adequate instructions for assembly, operation, and safe use of the product. This must include: (a) A discussion of all operation controls and a description of the effect of each control.

	(b) A schedule of maintenance necessary to keep the product in compliance with 21 CFR 1050.10. (c) Any safety precautions that may be necessary regarding ultrasound exposure. (d) A description (including textual discussion and diagrams, plots or photographs) of the spatial distribution of the radiated field. The description must include the statement that it applies for the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30°C and with line voltage variations in the range of ± 10%, or the rated value. (e) The uncertainties in magnitude, expressed in percentage error, of the ultrasonic frequency, effective radiating area, and (when applicable) the ratio of the temporal-maximum to temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length. (f) The error in indication of radiated power and intensity. (g) The error in indication of present treatment time. (h) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning "Caution -- use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."
Attach a copy of the user information to the preceding sections, clearly identified above. Click on the Add... button below to attach and select the files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Product Description

Note:	In order to adequately review a manufacturer's product, CDRH requires that a product report provide a thorough physical description of the product. Such a description must include:(a) Photographs or drawings or the generator and applicator.(b) A complete schematic diagram of the product.
Provide the information listed above as attachments. Click on the Add... button below to attach and select the files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Testing Programs

Note:	The information reported in this section will be used to determine whether the manufacturer's testing programs are adequate for certification (21 CFR 1010.2) and that the products are in compliance with the performance standard. Each item in this section must be addressed individually and in detail.

Incoming Component Testing

Note:	Fully describe all tests that are performed on components whose perfomance can affect compliance with this standard. This description should include but is not limited to:(a) Identify the component tested and its function.(b) State whether the component is tested on a 100 percent or sampling basis. If tested on a sampling basis, provide all sampling parameters and the basis for selecting the Acceptable Quality Level.(c) Describe the corrective action taken following unit or lot rejection (i.e.,

	return component to manufacturer, test 100 percent of components, increasesampling level). If the sampling level is increased, provide the complete rationale for this procedure, and any revised acceptance criteria.
Provide the above information as an attachment for each tested component. For example, if transducer crystals and timers are among the components tested, attach the description of the testing of crystals as one file attachment and the description of the testing of timers as the second file attachment, and so forth. Click on the Add... button to add and select the files to be attached.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Calibration of Test Instruments

Note:	Fully describe the instruments used in any test conducted to ensure compliance with this standard. This should include, but is not limited to, the following:(a) The manufacturer, model number, type (e.g., radiation force), accuracy, and resolution of the instrument used to measure ultrasonic power.(b) The procedure by which the above instrument is calibrated. Include a description of any calibrated source used, stating the accuracy and by whom calibrated.(c) The manufacturer, model number, and complete specifications of the hydrophone used to measure ultrasonic intensity.(d) A description of the scanning apparatus used to measure the spatial distribution of the radiated field.(e) A description of, and calibration procedures for, any other instrument used for compliance testing.
Provide the above information as attachments below. Click on the Add... button to add and select the files to be attached.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Production Testing

Note:	Fully describe all tests that are performed on the product during or after production to ensure compliance with this standard. The description of each test must include, but is not limited to, items (a) through (e) below. Note that part 1050.10(e) of 21 CFR requires that measurements of ultrasonic radiation be made with the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30°C, and with line voltage variations in the range of ±10% of the rated value. (a) Identify all instruments reported in the Calibration of Test Instruments section above that are used for the test. (b) State the sources and magnitudes of uncertainty in the test. (c) State whether the component or parameter is tested 100 percent or sampling basis. If tested on a sampling basis, include lot size, proportion of total production tested, method of sample selection to ensure randomness, and the rationale for sampling rather than testing on a 100 percent basis. It must be clearly demonstrated that such a sampling program will ensure compliance of all certified products. (d) Decribe the test procedure in detail, including any assumptions that are taken from the results. For example, in the description of the test for accuracy of indicated power, state the specific power levels at which the measurement is made, the error in indicated power at each point, and the range over which the average error is assumed to hold.

	(e) Describe the corrective action taken following unit or lot rejection (i.e., Increase sampling, test 100 percent).

Provide the above information as an attachment for each parameter tested. For example, present the description of the test for error in indicated power as a file attachment. Click on the Add... button to add and select the files to be attached. The parameters tested during production should include, but are not limited to:

(a) Error in indication of temporal-average ultrasonic power (CW units).

(b) Error in indication of temporal-maximum ultrasonic power (pulsed units).

(c) Error in measured value of effective radiating area.

(d) Error in the determination of the ratio of temporal-maximum effective intensity to temporal-average effective intensity.

(e) Error in indication of preset treatment time.

(f) Proper operation of manual and automatic treatment termination devices.(g) Proper operation of visual "ultrasound on" indicator.

(h) Proper operation of indicators of pulse duration, pulse repetition rate, and ultrasonic frequency (where applicable).

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Life Testing

Note:	Fully describe all tests that are performed on the product to ensure that it is capable of complying with the standard throughout its life. This should include, but is not limited to:(a) Sample size, frequency of sampling, and selection criteria.(b) Description of the test, including the sources and magnitudes of error, parameters measured or monitored, instruments used, and length of test or equivalent length of test.

Provide the above information as an attachment. Click on the Add... button below to add and select the files to be attached.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Provide an estimate of the useful life of the product (in years):	
Stop:	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.
Message:	Form FDA 3644 Guide for Preparing Product Reports for Ultrasonic Therapy Products (10/31/2013)