Form Approved: OMB No. 0910-0025
Expiration Date: July 31, 2020

FORM FDA 3760 (8/17)

Guide for Preparing Product Reports for Medical Ultrasound Products

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

More industry guidance and assistance can be found at the FDA homepage, see: http://www.fda.gov/Radiation-EmittingProducts/ .

Send your completed report to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling 1-800-638-2041.

Guide for Preparing Product Reports for Medical Ultrasound Products

September 1996

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Foreword

The Office of Compliance, Center for Devices and Radiological Health (CDRH) developed this guide. This guide will assist manufacturers[1] of electronic products which 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[2,3].

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. The submitter of the report will receive an acknowledgment letter with the accession number we assign 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. Also, a rejected report will not receive an accession number.

WE DO 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 report and to comply with all applicable importation requirements (21 CFR 1005). If there are deficiencies, we 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. We 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 (21 CFR 1003 - 1004) for products already introduced into commerce.

Please mail your reports to the address below (FDA can not process electronic submissions at this time). Provide the original report with appropriate signature(s) (no facsimiles, please). Provide extra copies only if this guide specifically requires them. Submit the report written in the English language. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy of the completed reports in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/Radiation-EmittingProducts/. No copyright exists for these guides. Reproduce these guides as needed. If you would like to comment on the reporting guides, web site, or future electronic submissions, you may direct the comments to the address below. If you need additional regulations for electronic products or medical devices, you should contact the Division of Small Manufacturers, International and Consumer Assistance by telephone at 1-800-638-2041 or by facsimile at 301-847-8149.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

E-MAIL ADDRESS: dsmica@fda.hhs.gov

MAILING ADDRESS (see 21 CFR 1002.7 for further information):

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

[1] **Manufacturer** (see 21) CFR § 1000.3(n)) means any person engaged in the business of manufacturing, assembling, or importing electronic products.

[2] **Accidental Radiation Occurrences:** 21 CFR 1002.20 requires manufacturers to immediately report accidental radiation occurrences (see 21 CFR 1000.3(a) for the definition).

[3] **Notification:** Title 21 CFR Part 1003 requires manufacturers to provide Notification of Defects or Failure to Comply. Send these notifications to the above address.

This Guide is provided to assist manufacturers in submitting product reports for medical ultrasound equipment (other than therapy or diagnostic) as required by Title 21 of the Code of Federal Regulations (21 CFR), Parts 1002.10 and 1002.11. It also serves as a basis for review of such reports by the Center for Devices and Radiological Health (CDRH).

A full product report must be submitted for each model or chassis family prior to the introduction into commerce. In addition, a premarket notification (510(k)) must also be submitted to the CDRH Office of Device Evaluation (ODE). Any changes made to the product design affecting radiation emission, transmission or leakage will require the submisson of a supplemental report, and may require the submission of a new 510(k). A new model family will require sending in a new product report.

Retain this guide for photocopying (or formatting for word processing) for use in filing all future reports. When the report is completed, make a copy for retention in your Device Master Record. When the report is received by CDRH, an acknowledgment letter will be sent to the submitter identifying an accession number. A unique accession number will be assigned for each model family; all additional models within that family, or changes to a previously reported model, will be assigned the same accession number with a unique supplement number. Please reference the accession number when additional information is submitted.

Product and supplemental reports should be forwarded to:

Center for Devices and Radiological Health
Document Mail Center – WO66-G609
ATTN: Electronic Product Reports
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling 1-800-638-2041.

Part 1002.50(3) of 21 CFR states that manufacturers of products for which there is no applicable performance standard under Parts 1020 through 1050 and for which an investigational device exemption (IDE) has been approved under Part 812.30, or for which a premarket approval application (PMA) has been approved in accordance with Part 814.44(d) are exempt from submitting all reports listed in Table 1 of Part 1002.1.

MEDICAL ULTRASOUND PRODUCT REPORT (31)

1. Manufacturer Identification

Manufacturer Name:

Address:

Telephone Number:

Email: Fax Number:

Place of Manufacture (if other than above):

Corresponding Official:

Title:

Signature:

U.S. Agent (if applicable):

Address:

Telephone Number:

Email: Fax Number:

Corresponding Official:

Title:

Signature:

Importer (if applicable):

Address:

Telephone Number:

Email: Fax Number:

Corresponding Official:

Title:

Signature:

Date of Submission:

NOTE: 21 CFR 1005.25 requires foreign manufacturers to assign a U.S. Agent to act on their behalf. The U.S. Agent may be an individual, a firm, or a domestic corporation.

2. Product Identification

Model Designation	Brand Name	Date Introduced into Commerce (mo/yr)

3. Product Applications and Uses

3.1 Describe the intended and known applications for each model reported. Provide applicable parts of manuals, sales brochures, or other documents that indicate intended and known applications.

4. Product Characteristics

4.1 Provide a brief description of operational characteristics that affect radiation emissions, transmission, exposure control or leakage.

4.2 Describe the physical or electrical characteristics incorporated into the product designed to control radiation emissions, transmission, leakage control, etc.

5. Product Testing

5.1 Describe the methods and procedures employed in testing and measuring each model with respect to electronic product radiation safety, including the control of unnecessary, secondary, or leakage electronic product radiation. Provide a copy of all applicable quality control procedures used for each model and the basis for selecting such testing and quality control procedures.

5.1.1 State the maximum amount of radiation output allowed by your design specifications.

5.1.2 State the measured values of radiation output (specify mean, standard deviation and measurement uncertainties).

5.1.3 State the number of units tested.

5.1.4 Describe the type of measuring equipment used for product testing.

5.2 For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

5.3 Provide sufficient results of the testing and measuring of electronic product radiation to enable the CDRH to determine the effectiveness of the methods and procedures used to accomplish the stated procedures.

6. User Information

For each model reported, attach a copy of the radiation specifications and user warnings provided to the user. Provide an example of all warning signs, labels, and instructions for the installation, operation, and use which relate to electronic product radiation safety. Include a copy of the user and/or service operating manual if it is available.