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FORM FDA 3759 (11/10)

Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products

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ABBREVIATED REPORTS ON RADIATION SAFETY OF NON-MEDICAL ULTRASONIC PRODUCTS

AUGUST1995

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spirng, 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. 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 determine that the product contains a radiation defect. We will notify the manufacturer if we make such a determination. CDRH may request that the manufacturer cease introduction into U.S. commerce until deficiencies are corrected. CDRH may also require the manufacturer 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 report 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 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 Director of the Office of Compliance (HFZ-300).

ABBREVIATED REPORTS FOR NON-MEDICAL ULTRASONIC PRODUCTS

General Information and use of this Guide

This guide for preparing abbreviated report for nonmedical ultrasonic products is issued by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) for manufacturers and importers of radiation emitting electronic products. Manufacturers and importers of ultrasonic products (see examples of products listed below) are subject to the requirements promulgated under Chapter V, Subchapter C - Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act. Applicable radiation reporting regulations are contained in Title 21 CFR, Part 1002.12. Further information regarding the reporting requirements can be obtained by calling the Division of Small Manufacturers Assistance at 1-800-638-2041.

Retain this guide for photocopying (or formatting for word processing) for use in filing all reports in the future. 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.

There are some foreign manufacturers that do not have a firm or a representative in the United States working on their behalf. Part 1005.25 requires foreign manufacturers to assign a manufacturer's U.S. Agent to act on their behalf. The U.S. Agent may be an individual, a firm, a domestic corporation or an importer.

Summary of requirements: An Abbreviated report must be filed for each model or chassis. Any major changes made to the product design affecting the radiation emission, transmission or leakage will require sending in a new Abbreviated Report.

Mail Reports to: Electronic Product Reports
Center for Devices and Radiological Health
Office of Compliance – WO66-G609
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 (301) 796-5710.

Examples of Non-Medical Ultrasonic Products Covered By This Abbreviated Report: nondestructive testing equipment, ranging and detection equipment, cleaners and other electronic products that emit infrasonic, sonic and ultrasonic radiation.

ABBREVIATED REPORT FOR NON-MEDICAL ULTRASONIC PRODUCTS

A. PRODUCT IDENTIFICATION (CHECK APPROPRIATE BOX):

[ ] Ranging or detecting (09) **[ ] Nondestructive testing (09)**

[ ] Cleaner (09)

[ ] Other (explain): _____

B. IDENTIFICATION OF FIRM:

B.1 Manufacturer Name: _____

Address: _____

_____

_____

Contact Official: _____

Title: _____

Signature: _____

Telephone: _____

B.2 Importer or U.S. Agent Name: _____

Address: _____

_____

_____

Contact Official: _____

Title: _____

Telephone: _____

B.3 Factory Location(s): _____

_____

_____

B.4 Date of this Report: _____

ABBREVIATED REPORT FOR NON-MEDICAL ULTRASONIC PRODUCTS

C. IDENTIFICATION OF MODEL(S) BEING REPORTED

Brand	Model Number

D. APPLICATIONS - USES (Describe the intended and known uses or applications of each model):

E. OPERATIONAL CHARACTERISTICS (Provide a brief description of operational characteristics that affect radiation emissions, transmission, or leakage or that control exposure):

F. RADIATION LEVELS (Fill in the answers or check where indicated)

F.1 The maximum amount of radiation output allowed by your design is: _____ .

F.2 The frequency of the output radiation is: _____ .

F.3 The product operates [ ] continuously or [ ] has a duty cycle of _____ .

F.4 Does the product produce modulation of the output radiation? [ ] Yes [ ] No

If yes, describe all types of modulation and how it is produced: _____

_____

F.5 Does the product meet any known radiation standards? If yes, give the name of the performance or radiation standard:

F.6 Technical Information Attached - Attach technical information including the following: (a) operation and maintenance manual, (b) servicing manual, (c) performance or design data on the product, (d) wiring diagrams or schematics, and (e) appropriate warnings and labels with instructions to avoid unnecessary radiation exposure.