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FORM FDA 4004 (11/20)

Guidance for the Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use

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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 ABBREVIATED REPORTS OF MICROWAVE AND RF EMITTING ELECTRONIC PRODUCTS INTENDED FOR MEDICAL USE

September 1996

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Silver Spring, MD 20993

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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: DICE@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.

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GENERAL INFORMATION

This guide for the submission of Abbreviated Reports 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 of these products are subject to the requirements promulgated under Subchapter C - Electronic Product Radiation Control of the Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act). Applicable radiation reporting regulations are contained in Title 21 of the Code of Federal Regulations (21 CFR), Part 1002. In an effort to shorten the reporting and recordkeeping requirements of 21 CFR 1002, an abbreviated report form has been created for certain radiation emitting electronic products such as those listed below.

Manufacturers and/or importers of these products will no longer be required to maintain test records or distribution records, or to submit full product or annual reports. The issuance of the abbreviated form does not preclude the FDA from requesting additional information necessary to determine whether the manufacturer has acted or is acting in compliance.

This abbreviated form is applicable to, but not limited to, the following medical products:

(a) microwave diathermy devices

(b) microwave heating and drying systems (i.e. blood warmers, sterilizers, etc.)

(c) radiofrequency (RF) electromagnetic induction or dielectric heating devices [2 MHz to 500 MHz] (i.e. RF diathermy, RF cautery devices, RF lesion generators and probes, etc.)

Retain this guide for photocopying (or formatting for wordprocessing) for use in filing all reports in the future. When the report is completed, make a copy and retain the copy in your file.

When the report is received by CDRH, an acknowledgement letter will be sent to the submitter, with an identifying 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. Subsequent to filing an abbreviated report to CDRH, any changes made to the product design affecting the radiation emission, transmission or leakage will require sending *in* a new abbreviated report.

There are a number of 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 designate a U.S. Agent to act on their behalf. The U.S. Agent may be an individual, a firm or a domestic corporation.

REMINDER - Part 1003 - Discovery of Defect or Failure of Compliance by Manufacturer:

Any manufacturer who discovers that a product defect exists in any radiation emitting electronic product produced, assembled, or imported by him, that may result in a radiation injury, including genetic injury to any person, must notify CDRH immediately.

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MICROWAVE/RF ABBREVIATED PRODUCT REPORT (03/02)

1. Manufacturer Identification

Name _____

Address _____

_____

Telephone _____ Email _____

Place of Manufacture if Other than Above _____

Corresponding Official:

Title _____

Signature _____

U.S. Agent (if applicable)

Address _____

_____

Telephone _____ Email _____

Corresponding Official:

Title _____

Signature _____

Importer (if applicable)

Address _____

_____

Telephone _____ Email _____

Corresponding Official:

Title _____

Signature _____

Date of submission: _____

2. Report Identification

Indicate the type of product that you are reporting.

[ ] Microwave Diathermy (03)

[ ] Microwave Heating or Drying System (02)

[ ] Dielectric or Induction Heating Devices

Please be aware that the products listed above may be considered medical devices under the Federal, Food, Drug and Cosmetic Act (FFDCA). If so, has your firm filed a Premarket Notification {510 (k)} with the Center for Devices and Radiological Health's (CDRH) Office of Device Evaluation (ODE)?

3. Model Family Identification

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

4. Product Information

The following information should be submitted as an attachment to this page. Identify each response with the section being completed, i.e. Attachment 4.1 would be the response to section 4.1, etc.

4.1 Describe the intended and known uses of each model. Describe the expected use environment and user training. Provide copies of appropriate sections of operating manuals, sales brochures, or any other available promotional materials.

4.2 Provide a description of operational characteristics that affect radiation emissions, transmissions, or leakage, or control exposure.

4.2.1 State the output frequency(ies) of operation (include signal modulation and rates for intentional emitters). For pulsed operation, state the duty cycle(s) and all types of modulation of the output radiation, including duration, repetition rate and peak amplitude of power.

4.2.2 Give the average and maximum power output of the device, and the method(s) of assessment. List all major components that emit radiation and their operating frequency(ies). Include a description of the approximate field strength to distance ratio.

4.2.3 Describe the power output indicator(s), and the relationship between the meter indication and the radiation output. Include linearity and accuracy of the output indicator(s).

4.3 In accordance with your design specifications, describe the maximum amount of radiation emission permitted from a fully assembled product. Give the design specification for leakage from all openings, generator, waveguide(s), antennae, etc., prior to purchase, and any time thereafter.

4.4 Describe the physical or electrical features incorporated in the design of the product (such as shielding, safety interlocks, timers) to ensure the product meets your radiation safety specifications.