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FORM FDA 3662 (7/07)

A Guide for the Submission of an Abbreviated Radiation Safety Report on Cephalometric Devices Intended for Diagnostic 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.

A GUIDE FOR THE SUBMISSION OF

AN ABBREVIATED RADIATION SAFETY REPORT ON

CEPHALOMETRIC DEVICES

INTENDED FOR DIAGNOSTIC USE

MARCH 1996

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MD 20850

Foreword

This guide was developed by the Office of Compliance, Center for Devices and Radiological Health (CDRH), to assist electronic product manufacturers in providing adequate reporting of radiation safety testing and compliance with performance standards. Reporting requirements are specified in Title 21 of the Code of Federal Regulations (CFR), Part 1002.

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7), or contain a justification why it was not followed. CDRH may reject an incomplete report and return it for completion. When the report is adequate for filing, it will be logged into the CDRH computer system and assigned an accession number. 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.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with the applicable standard (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. The manufacturer is required to submit the report (21 CFR 1002) and to comply with all applicable importation requirements (21 CFR 1005) prior to the shipment of products in interstate commerce. If there are deficiencies, we may disapprove the firm's quality control and testing program or determine that the product contains a radiation defect or fails to comply with a standard. We will notify the manufacturer if we make such a determination. Then the manufacturer may be required 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.

We are making our reporting guides available on the CDRH Electronic Docket, for downloading and reproduction. They are not copyrighted and may be reproduced as needed. The telephone number for access to the CDRH Electronic Docket via your personal computer's modem is 1-800-252-1366.

Please mail your reports to the address below (electronic submissions cannot be processed yet). Provide one original

IN ENGLISH (no facsimile, please) unless specified otherwise in the guide. Make a copy of the completed report for your records. If you would like to comment on the reporting guides or the electronic docket or future electronic submissions, you may direct the comments to the same address. If you need additional regulations for electronic products or medical devices, contact the Division of Small Manufacturers Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

MAILING ADDRESS:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE (HFZ-307)
ATTN: ELECTRONIC PRODUCT REPORTS
2098 GAITHER ROAD
ROCKVILLE MD 20850

INTRODUCTION

This guide presents an outline for a manufacturer to follow in preparing an abbreviated report, or abbreviated supplemental report, for cephalometric devices intended for use with diagnostic x-ray equipment. These certifiable components are subject to the Performance Standard, 21 CFR 1020.30 and 1020.31.

The focus of the guide is to identify the pertinent information required by the Food and Drug Administration for the certification of cephalometric devices. Information submitted will be considered toward fulfillment of the requirements of the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602).

This reporting guide is to be used as a replacement for other previous guides that have been developed for presentation of product (initial) report and supplemental report data. This guide applies only to the manufacture and certification of cephalometric devices. It can not be used for other certifiable components.

NOTE: All reports submitted under this abbreviated guide must be in English.

PART 100 - IDENTIFICATION

101.0 REPORT IDENTIFICATION

Confirm that this report is submitted pursuant to paragraph (c)(1) of section 1002.61, and state the following:

101.1 Report type (product (initial) report or supplement to CDRH Accession #_____)

101.2 Identification of certifying manufacturer name and address which should appear on the product label.

101.3 Name, address and telephone number of submitter and identification of corresponding official.

101.4 If the address listed in 101.2 above is not the manufacturing cite where certification testing is documented, then provide the name and address of that location. Indicate how this manufacturing site is identified on your label.

102.0 PRODUCT IDENTIFICATION

102.1 Provide the model designation as would appear on the component identification label, for each cephalometric component being certified in this report.

102.2 If the model designation(s) reported above is sold under a name other than your own, provide the model designation and name and address of each company under whose name the product is sold or labeled.

102.3 For each model designation listed under 102.1 and/or 102.2, provide an exact replica of all labeling completed with the following items filled in as would be found on the component when shipped:

(a) certification statement;
(b) name and address of manufacturer;
(c) date and place of manufacture;
(d) model designation and sample serial number; and
(e) a drawing indicating the location of the label.

102.4 Attach the following information as appendices:

(a) assembler's manual -- Appendix A
(b) user's manual -- Appendix B

PART 200 - COMPONENT DESCRIPTION FOR CEPHALOMETRIC DEVICES

This section should be completed for each cephalometric device listed in section 102.1 of PART 100 that includes a beam-limiting device (BLD) as an integral design feature.

200.1 For each model cephalometric device, indicate the design SID, and the image receptor size.

200.2 Describe the means for limiting and/or centering the x-ray field.

200.3 If a light field is used to define the perimeter of the x-ray field, then it must meet the requirements of 21 CFR 1020.31(d)(2).

PART 300 - QUALITY CONTROL TESTING
CEPHALOMETRIC DEVICES

This section requires documentation and test data to assure that cephalometric devices that include beam-limiting devices (BLDs) and which function at one SID and image receptor size, meet the requirement to limit the x-ray field at the plane of the image receptor to dimensions no greater than those of the image receptor, or the requirement to align the x-ray field such that at the plane of the image receptor, the x-ray field does not extend beyond any edge of the image receptor. When prototype and production testing are identical, refer to production testing.

300.1 Critical Parameters - As a result of inherent inaccuracies of test procedures and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

300.2 Prototype Testing

a. Describe the test method used to insure that x-ray is properly aligned and centered with the image receptor.

b. Identify all test instruments by manufacturer and model number.

c. Describe the procedure for periodic calibration of the test instruments.

d. Provide prototype test data and rejection limits.

e. If a light field is used to define the perimeter of the x-ray field, describe in detail the test method used to insure compliance with the light field requirements for light illuminance, edge contrast ratio, and alignment of visually defined field.

300.3 Production Testing

a. Describe the test method used to insure that x-ray is properly aligned and centered with the image receptor.

b. Identify all test instruments by manufacturer and model number.

c. Describe the procedure for periodic calibration of the test instruments.

d. Provide production test data and rejection limits.

e. If a light field is used to define the perimeter of the x-ray field, describe in detail the test method used to insure compliance with the light field requirements for light illuminance, edge contrast ratio, and alignment of visually defined field.