K052136

510(k) Summary

FOR

ANRAD Corporation

GR17 Digital Detector

Date:	August 17, 2005
Submitter's Name:	ANRAD Corporation
Submitter's Address:	4950 Levy Street Saint-Laurent (Québec) Canada H4R 2P1
Submitter's Contact:	Donald J Sherratt Regulatory Affairs Manager Analogic Corporation 8 Centennial Drive Peabody, MA 01960 Telephone (978) 977-3000 extension 4075 Facsimile (978) 977-6808
Establishment Registration Number:	Applied For
Device Proprietary Name:	GR17 Digital Detector
Common Name:	Solid State X-ray Imager
Regulatory Class:	II (per 21 CFR 892.1650)
Predicate Devices:	ANRAD Corporation GR17 (K042821) DRC (formerly Sterling Diagnostic Imaging) (K973206)
Reason for Submission:	Modification to specificaton for defective pixel detection and correction.
Description of device:	The GR17 is a 17" x 17" Flat Panel Digital Radiographic Detector for General Radiographic Use. It uses amorphous Selenium (a-Se) as the primary photoconductor.
Summary of Intended Uses:	The GR17 is an amorphous Selenium based direct conversion Digital Radiography (DR) detector intended for use by a qualified/trained doctor or technician and is designed to generate images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. The GR17 is not used for mammography.
Technological Characteristics:	The GR17 employs the same technological characteristics as the predicate devices, differing only in the size of the detector area. The GR17 is 17" X 17" and the DRC detector is 17" X 14".

11 DESIGN CONTROLS

The design controls continue to be controlled by ANRAD Corporation. A declaration has been provided in this submission. See page xi of this submission.

11.1 Risk and Hazard Analysis

The Risk and Hazard Analysis, was performed following the change to the algorithm for detection of bad pixels. The conclusion of the Risk and Hazard Analysis is that all hazards that have been adequately mitigated. All identified conditions have been resolved through at least one of the following:

- Mechanical Design
- Hardware (Electrical) Design
- Software Design
- Training
- Operating Manual
- Installation Manual

The risk and hazards analysis was reviewed for the purpose of identifying the MODIFICATION RISKS, that is, hazards that could possibly be affected by the modifications and any new hazards that could possibly be introduced by the modifications. The selections of the individual verification and validation tests were chosen to cover the risks identified in this review of the modifications. The hazard analysis is provided in APPENDIX B.

11.2 Pixel Defects (satisfies section C10 of guidance document)

See APPENDIX D.

11.3 Verification Tests

The particular verification tests were chosen to ensure test coverage of the areas changed in the specifications for pixel defects. Pixel defect correction Comparison tests and Results are provided in APPENDIX E.

11.4 Software Requirements – Level of Concern

In accordance with FDA Guidance Document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 11, 2005", the software for the GR17 Detector is considered "Minor Level of Concern."

The determination was based on answering "No" to all of the key questions located in Table 1 (Major Level of Concern) and Table 2 (Moderate Level of Concern) of the FDA Guidance Document.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

ANRAD Corporation
% Mr. Donald J. Sherratt
Regulatory Affairs Manager
Analogic Corporation
8 Centennial Drive
PEABODY MA 01960

AUG 23 2013

Re: K052136
Trade/Device Name: GR17 Digital Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 1, 2005
Received: August 5, 2005

Dear Mr. Sherratt:

This letter corrects our substantially equivalent letter of August 25, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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510(k) Number K052136:

Device Name: GR17 Digital Detector

Indications For Use:

The GR17 is a selenium-based direct conversion DR detector intended for use by a qualified/trained doctor or technician and is designed to perform radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. The GR17 is not used for mammography.

NOTE: The Indications For Use has not changed since the original 510(k).

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)