K042821

OCT 2 2 2004

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# 510(k) Summary
# For
# ANRAD CORPORATION
# GR17 Digital Detector

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92

1. **Submitter's Name and Address:**

   ANRAD CORPORATION
   4950 Levy Street
   Saint-Laurent (Québec) Canada H4R 2P1

2. **Date this Summary was Prepared:**

   September 24, 2004

3. **Submission Correspondent:**

   Donald J Sherratt
   Regulatory Affairs Manager
   Analogic Corporation
   8 Centennial Drive
   Peabody
   MA 01960
   Telephone (978) 977-3000 extension 3049
   Facsimile (978) 977-6808

4. **Device Name:**

   | | |
   |---|---|
   | Proprietary or Trade Name: | GR17 Digital Detector |
   | Common Name: | Solid State X-Ray Imager (Flat Panel / Digital Imager) |
   | | Classification Name: Solid State X-Ray Imager |
   | Classification Panel: | Radiology |

5. **Predicate Devices:**

   The legally marketed devices to which equivalence is being claimed are:

   The Sterling Diagnostic Imaging Direct Radiography (K973206) and the Fuji Computed Radiography System FCR9000HQ (K951373).

## 6. Device Description

The GR17 is a 17 inch by 17 inch digital detector. It is intended to convert X-rays into electrical signals to create usable images for diagnostic use. The dimensions of the GR17 are below:

| | |
|---|---|
| Overall length | 574 mm |
| Overall width | 502 mm |
| Overall height | 32.3 mm |
| Weight | 10.5 kg |

**Table 4: GR17 Dimensions**

## 7. Intended Use

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 radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

## 8. Comparison of Technological Characteristics:

The design of the GR17 Digital Detector has the same technological characteristics as the predicate devices.

## 9. Clinical and Non-Clinical Testing

### 9.1 Conclusions from Clinical Testing

Based on the Clinical Study Report dated September 8, 2004, the GR17 Digital Detector is substantially equivalent to the predicate device.

### 9.2 Conclusions from Non-clinical Testing

The testing of the GR17 Digital Detector demonstrates that the performance is substantially equivalent to the predicate devices cited above.

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. Daniel W. Lehtonen
Staff Engineer-Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

AUG 23 2013

Re: K042821
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: October 8, 2004
Received: October 12, 2004

Dear Mr. Lehtonen:

This letter corrects our substantially equivalent letter of October 22, 2004.

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 K042821:

Device Name: GR17 Digital Detector

Indications For Use:

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 radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042821