K070829

14 510(K) SUMMARY

510(k) Summary MAY - 9 2007
For
Analogic Corporation
SynePix 4600 Detector

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

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

   Analogic Corporation
   8 Centennial Drive
   Peabody, MA, 01960

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

   March 23, 2007

3. **Submission Correspondent:**

   Donald J Sherratt
   Director of Corporate Regulatory Affairs
   Analogic Corporation
   8 Centennial Drive
   Peabody
   MA 01960
   Telephone (978) 977-3000 extension 4075
   Facsimile (978) 977-6808

4. **Device Name:**

Proprietary or Trade Name:	SynePix 4600 Detector
Common Name:	Solid State X-Ray Imager (Flat Panel / Digital Imager) Classification Name: Solid State X-Ray Imager
Classification Panel:	Radiology
Code of Federal Regulations:	892.1650
Product Code:	MQB

5. **Predicate Devices:**

   The legally marketed device to which equivalence is being claimed is:

   Kodak DirectView DR System Detector marketed by Eastman Kodak Company and cleared under K051483.

6. Device Description

The SynePix 4600 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 SynePix 4600 are below:

Overall length	488 mm
Overall width	533 mm
Overall thickness	45 mm
Weight	18 kg

Table 14: SynePix 4600 Dimensions

7. Intended Use

The SynePix 4600 is Thallium-doped Cesium Iodide and amorphous Silicon (a-Si) 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 SynePix 4600 Detector has the same technological characteristics as the predicate device.

9. Conclusions from Non-clinical Testing

The testing of the SynePix 4600 Detector demonstrates that the performance is substantially equivalent to the predicate device 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

Mr. Donald J. Sherratt
Director of Corporate Regulatory Affairs
ANALOGIC Corporation
8 Centennial Drive
Centennial Industrial Park
PEABODY MA 01960

AUG 23 2013

Re: K070829
Trade/Device Name: SynePix 4600 Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 23, 2007
Received: March 26, 2007

Dear Mr. Sherratt:

This letter corrects our substantially equivalent letter of May 9, 2007.

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

ANALOGIC®

510(k) Number K070829:

Device Name: SynePix 4600 Detector

Indications For Use:

The SynePix 4600 is Thallium-doped Cesium Iodide and amorphous Silicon (a-Si) 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.

The detector will be used with Analogic AN6255 and AN6265 (SyneRad Omni and SyneRad Omni RT) Systems. The AN6255 has a single tall stand and single detector, the AN6265 is a dual detector system with a tall stand and short stand.

The detector is not for use for mammography.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070829