K073124

Collimare

NOV 16 2007

510(k) Summary

Date: August 24, 2007 **510(k) Number** _____

Submitter: Collimare, LLC
13406 W 60TH PL
Arvada, CO 80004

Contact: Howard C. Thomas, President

Phone: (303) 955-3091

Fax: (303) 955-3092

Common Device Name: Manual or Automatic Collimator

Trade Name: Collimare "Collimator Family"

Classification Name: Diagnostic X-ray Beam Limiting Device

Classification Regulation Number: IZX & IZW

Classification Committee/Panel: Radiology

Predicate Devices: X-Ray Collimating Devices K810598 Manufactured by Eureka X-Ray Tube AXT150MC K972966 Manufactured by Applied X-Ray Technologies

Description: The Collimare "Collimator Family" and/or variations is used to control the x-ray beam for use on diagnostic imaging equipment. The intended usage is all portable/fixed, manual and automatic, Radiographic, Fluoroscopic, rectangular, square and/or circular shuttering. It can encompass a light simulation, spectral filters, wedge filters, input port shuttering, dose measurement, laser alignment indicating lines and/or mechanical or digital SID measurement.

Intended Use: The Collimare "Collimator Family" and/or variations is used to control the x-ray beam for use on diagnostic imaging equipment during radiographic and fluoroscopic procedures. It is designed to be adapted to various x-ray systems.

Performance Standards / Safety Information: X-Ray Performance Standard 21 CFR Section 1020.30, .31 & .32 // UL 60601-1 Standard for Safety, Medical Electrical Equipment // IEC 60825-1 Ed: 1 Safety of laser products – Part 1: Equipment classification and requirements

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

Collimare LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K073124
Trade/Device Name: Collimare "Collimator Family"
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray beam-limiting device
Regulatory Class: II
Product Code: IZW and IZX
Dated: November 5, 2007
Received: November 6, 2007

Dear Mr. Job:

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 either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073124

Device Name: Collimare "Collimator Family"

Indications for Use:

The Collimare "Collimator Family" and/or variations is used to control the x-ray beam for use on diagnostic imaging equipment during radiographic and fluoroscopic procedures. It is designed to be adapted to various x-ray systems.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073124