

K073124



**Collimare**

NOV 16 2007

## 510(k) Summary

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

**Submitter:** Collimare, LLC  
13406 W 60<sup>TH</sup> 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

**Collimare, LLC**  
13406 W 60<sup>TH</sup> PL  
Arvada, CO 80004  
P: 303.955.3091  
F: 303.955.3092



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 16 2007

Collimare LLC  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> 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  
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): KC73124

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.

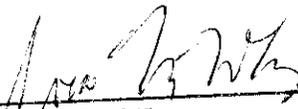
Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(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