JUL 2 1 2003 K031597

Philips Medical Systems

510(k) SUMMARY

Company name: Address:	Philips Medical Systems North America Company 22100 Bothell Everett Highway P.O. Box 3003 Bothell, WA 98041-3003, U.S.A.
Registration No.:	1217116
Contact person: Telephone No.:	Lynn Harmer (425) 487-7312
Date prepared:	2003-03-20
Device (trade) name:	Dunlee "FORMAT" collimator family
Classification name:	Diagnostic X-ray Beam-Limiting Device (21CFR892.1610), Class II (Procodes: 90 IZW & 90 IZX).
Common/usual name:	Automatic resp. Manual Radiographic Collimator.

Predicate device:

- The Dunlee manual "FORMAT M" collimators are substantially equivalent to the pre-amendment manual collimators with codenumbers 9804 602 60501 and 9804 602 61501 (BRH accession number 7410693), manufactured by Philips Medical Systems.
- The Dunlee automatic "FORMAT A" collimators are substantially equivalent to the NICOL collimator family manufactured by Philips Medical Systems, which has been determined to be substantially equivalent to legally marketed predicate devices under number K990423.

Device description:

The Dunlee "FORMAT" collimator family is a family of Beam-Limiting Devices, which comprises both manual and automatic collimators. The manual collimators are to be used in diagnostic radiographic X-ray systems, and the automatic collimators are to be used in both diagnostic fluoroscopy X-ray systems and diagnostic radiographic X-ray systems.

Intended use:

- The Dunlee "FORMAT" collimator family restricts the dimensions of the diagnostic X-ray field by limiting the size of the primary X-ray beam.
- The Dunlee manual "FORMAT M" collimators are intended for use in diagnostic X-ray systems during radiographic examinations.
- The Dunlee automatic "FORMAT A" collimators are intended for use in diagnostic X-ray systems during radiographic and fluoroscopic examinations.

Safety information:

- The Dunlee "FORMAT" collimator family will comply with the applicable requirements of the performance standards for ionizing radiation emitting products (21CFR1020.30, 21CFR1020.31 and 21CFR1020.32).
- The Dunlee "FORMAT" collimator family will comply with national safety standards UL 2601-1 and CAN/CSA-C22.2 no. 601-1.
- The Dunlee "FORMAT" collimator family will comply with international safety standards IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-28 and IEC 60601-2-43.

Conclusion:

The Dunlee "FORMAT" collimator family does not introduce any new indications for use, nor does the use of the devices result in any new potential hazard. Dunlee considers the FORMAT collimator family to be substantially equivalent with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K031597
Trade/Device Name: Dunlee "Format" Collimator Family
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray beam-limiting device
Regulatory Class: II
Product Code: 90 IZW and IZX
Dated: May 19, 2003
Received: June 9, 2003

Dear Ms. Harmer:

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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K031597

Device Name: DUNLEE "FORMAT" COLLIMATOR FAMILY

The Format collimator family will be used in Radiography, Fluoroscopy, Cardio and Vascular X-ray systems. It has the following functionality (configuration dependant):

- X-ray field limitation (rectangular and circular); rectangular shuttering in some configurations with direct user control at the collimator head (direct shutter control)
- Simulation of X-ray field by a light field
- Measurement of source image distance (with an electronic or mechanical ruler)
- Spectral filtering
- Wedge filtering (semi-transparent filtering)
- Dose measurement (Area Exposure Product Measurement device)

Format family consists of a manual version and automatic versions. The product configuration of the automatic version depends on the configuration of the X-ray system. It's a modular concept in which collimator functionalities can be added for radiographic or fluoroscopy applications.

The automatic collimators have an ISO-CAN software interface with the system through which they receive system commands at open-close level.

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031597

Prescription Use (Per 21 CFR 801.109)