K073632

ARCOMA

510 (k) Summery

Date of summery: November 26, 2007

JAN 10 2008

Submitter/Manufacturer/Applicant:
Arcoma AB
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Sweden
Contact person:
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Device Name and Classification

Trade name	Arcoma, Intuition
Classification name	Stationary x-ray system
Review Panel	Radiology
Product Code	KPR
Regulation Number	892.1680
Device classification	Class II

Predicate device

1. Q-Rad Radiographic System manufactured by Quantum Medical Imaging LLC, K011486
2. Xplorer 2200 Digital Radiographic System manufactured by Imaging Dynamics Company Ltd, K063039
3. DAR7000 RADspeed SAFIRE manufactured by Shimadzu Corporation, K050925

Device description

The 0170 Intuition is a stationary x-ray system with a ceiling mounted tube stand, a floor mounted table and a wall stand that has a floor mounted column with a detector holder.
The ceiling stand and the table has automatic movements for up and downs, other movements are manual.
The standard equipment includes a graphic display showing X-ray tube rotation and film focus or source image distance.

Intended use

The 0170 Intuition is a stationery x-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment.

The 0170 Intuition is not intended for mammography

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2008

ARCOMA AB
% Mr. Jay Y. Kogoma
Official Correspondent
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K073632
Trade/Device Name: Intuition, Model 0170
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: December 21, 2007
Received: December 26, 2007

Dear Mr. Kogoma:

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

ARCOMA

Statement of Indication for Use

510(k) Number: K 073632

Device Name: Intuition, Model 0170

The 0170 Intuition is a stationery x-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment.

The 0170 Intuition is not intended for mammography.

Prescription Use ___X___ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073632

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