K111299

Tab 4

JUL 20 2011

510(k) Summary

Submitter

Xoft, an iCAD Company
Establishment Registration Number: 3005594788
345 Potrero Ave
Sunnyvale, CA 94085
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Summary was prepared on May 25, 2011

Name of Device

Trade name:	Axxent® Radiation Shield - Rigid
Common name:	Radiation Shield for Radiation Therapy
Classification Name:	X-ray Radiation Therapy System and Accessories 90 JAD (per 21 CFR 892.5900)

Predicate Device

Device Name	Premarket Notification
Photoelectron (now Carl Zeiss Surgical) Photon Radiosurgery System Radiation Shield	Class I, but submitted as an accessory in K992577

Device Description

The Axxent Radiation Shield - Rigid is an optional radiation shielding accessory to the Axxent Electronic Brachytherapy System (cleared under K072683) intended to protect tissue and/or organs from unwanted radiation. It is a rigid stainless steel pad placed over the area requiring shielding. It can be used on external patient surfaces, such as skin, as well internally during Intraoperative Radiation Therapy (IORT).

The Axxent Radiation Shield - Rigid is fabricated entirely from 316L stainless steel (UNS S31603, ASTM A240/A240M). The shield is available in circular and ellipsoidal shapes in a range of various sizes.

The Axxent Radiation Shield - Rigid is provided non-sterile and can be reused. The user must sterilize the device using steam sterilization before each use.

Intended Use

The Axxent Electronic Brachytherapy System is intended to deliver high dose rate X-ray radiation for brachytherapy.

Summary of the Technological Characteristics

The technological characteristics of the Axxent Radiation Shield - Rigid are the same as the Photon Radiosurgery System (PRS) Radiation Shield. The PRS radiation shield is a Class I device that was submitted as an accessory to the PRS under premarket clearance K992577. The device is substantially equivalent in terms of design, materials, principles of operation, and product specification to the predicate device.

Substantial Equivalence

Comparison Table of Predicate and Subject Device

Characteristic	PRS Radiation Shield	Axxent Radiation Shield - Rigid
510(k) Number	**Class I, but submitted as an accessory under K992577**	**Subject device**
Indications for Use	Use of the Radiation Shield is indicated in cases in which protection of tissue and/or organs from x-radiation is desired.	Use of the Axxent Radiation Shield - Rigid is indicated in cases in which protection of tissue and/or organs from x-radiation is desired. The Axxent Radiation Shield - Rigid can be used externally and internally, such as during intraoperative radiation therapy (IORT) when the treatment site is exposed surgically.
Can be used internally	Yes	Yes
Multiple Shapes	Yes, multiple semi-spherical	Yes, available in circular and ellipsoidal shapes
Sizes	1.5 to 5.0cm in diameter	Diameters ranging from 3 cm to 7 cm for circular shapes. Minor and major axes ranging from 3 cm to 12 cm for ellipsoidal shapes.
Material	Tungsten-filled silicone resin	316L Stainless Steel (UNS S31603, ASTM A240/A240M)
Sterilization	Provided sterile, gamma	Provided non-sterile, required to steam sterilization
Lead Equivalency	0.05mm at 50kVp	Not less than 0.20 mm at 50 kVp
For Use With	Photoelectron (now Carl Zeiss Surgical) Photon Radiosurgery System	Axxent Electronic Brachytherapy System

Performance Testing

The attenuation of the Axxent Radiation Shield - Rigid is greater than 99% at 50kVp. See Tab 12 for the method used to determine the attenuation.

The Axxent Radiation Shield – Rigid was tested to withstand at least 50 cycles of cleaning and sterilization according to the instruction in the IFU. See Tab 13 for device lifecycle testing.

The Axxent Radiation Shield – Rigid device was tested to show that it did not shed material during worst case clinical usage. See Tab14 for material shedding tests conducted on the device.

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. Steve Lin
Director of Regulatory Affairs and Quality Assurance
Xoft, an iCAD Company
345 Potrero Avenue
SUNNYVALE CA 94085

JUL 20 2011

Re: K111299
Trade/Device Name: Axxent® Radiation Shield - Rigid
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: July 6, 2011
Received: July 7, 2011

Dear Mr. Lin:

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,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111299

Device Name: Axxent® Radiation Shield - Rigid

Indications for Use:

Use of the Axxent Radiation Shield - Rigid is indicated in cases in which protection of tissue and/or organs from x-radiation is desired. The Axxent Radiation Shield - Rigid can be used externally and internally, such as during intraoperative radiation therapy (IORT) when the treatment site is exposed surgically.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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