K090417

JUN 23 2009

Tab 4

510(k) Summary

Submitter

Xoft, Inc.
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Sunnyvale, CA 94085
Contact Name: Steve Lin
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Summary was prepared on February 17, 2009

Name of Device

Trade name:	Axxent® FlexiShield Mini
Common name:	Beam Blocks for Radiation Therapy
Classification Name:	Radiation Therapy Beam Shaping Block 90 IXI (per 21 CFR 892.5710)

Predicate Device

Device Name	Premarket Notification
Arplay Medical Lead Blocks	K010172

Device Description

The Axxent FlexiShield Mini is intended to shape the beam from a low energy radiation therapy source up to 50kVp. It is a flexible pad placed over the surface requiring shielding that can be cut by the customer to shape the radiation therapy beam. It can be used on external patient surfaces, as well as internally during Intraoperative Radiation Therapy (IORT).

The Axxent FlexiShield Mini is fabricated from a composite made from tungsten and silicone rubber. The pad is available in a circular shape with a diameter of 12.7 cm and a thickness of .1 cm.

The Axxent FlexiShield Mini is provided non-sterile. The device is steam sterilizable.

Intended Use

To shape the beam from a low energy radiation therapy source up to 50kVp.

Summary of the Technological Characteristics

The technological characteristics of the Axxent FlexiShield Mini are the same as the Arplay Medical Lead Blocks approved in K010172. The device is substantially equivalent in terms of design, materials, principles of operation, and product specification to the predicate device. A comparison table is available in Tab 8.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

Mr. Steve Lin
Director of Regulatory Affairs and Quality Assurance
Xoft, Inc.
345 Potrero Ave.
SUNNYVALE CA 94085

Re: K090417
Trade/Device Name: Axxent® FlexiShield Mini
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: June 5, 2009
Received: June 9, 2009

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting 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: K090417

Device Name: Axxent® FlexiShield Mini

Indications for Use:

To shape the beam from a low energy radiation therapy source up to 50kVp.

Prescription Use__X__ AND/OR Over-The Counter Use____
(Per 21 CFR 801 subpart D) (Per 21 CFR 801 subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090417