FEB 11 2009

Tab 4

510(k) Summary

Submitter

Xoft, Inc.
345 Potrero Ave
Sunnyvale, CA 94085
Contact Name: Steve Lin
Phone Number: (408) 419-2341
Fax Number: (408) 419-2301
Email: steve.lin@xoftinc.com
Summary was prepared on December 15, 2008

Name of Device

Trade name:	Axxent® Surface Applicator
Common name:	Brachytherapy Surface Applicator
Classification Name:	X-Ray Radiation Therapy System and Accessories 90 JAD (per 21 CFR 892.5900)

Predicate Device

Device Name	Premarket Notification
Nucletron Valencia Skin Applicator Set	K073107

Device Description

The Axxent Surface Applicator is a component of the Axxent Electronic Brachytherapy System which utilizes a proprietary miniaturized x-ray source and does not require radioactive isotopes. The applicator allows the Axxent HDR X-ray Source to deliver high-dose rate, low energy radiation treatment to skin and tissue surfaces. The Axxent HDR X-ray Source mimics the penetration and dose characteristics of Iridium-192 within the treatment target. The Axxent Surface Applicator is provided in multiple circular aperture sizes to accommodate a range of lesion sizes. The applicators are reusable and sterilizable. Single use disposable end caps are provided to help flatten the treatment surface.

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 Surface Applicator are the same as the Nucletron Valencia Skin Applicator approved in K073107. 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

FEB 11 2009

Mr. Steve Lin
Regulatory Manager
Xoft, Inc.
345 Potrero Ave.
SUNNYVALE CA 94085

Re: K083734
Trade/Device Name: Axxent® Surface Applicator
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: December 15, 2008
Received: December 17, 2008

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 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 os 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 this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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 Manufactures, 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.suppot/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: K083734

Device Name: Axxent® Surface Applicator

Indications for Use:

The Axxent Surface Applicator is indicated for use with the Axxent Electronic Brachytherapy System to deliver surface brachytherapy, including Intraoperative Radiation Therapy (IORT) during the time the treatment site is exposed surgically.

Prescription Use__X__ (Per 21 CFR 801 subpart D)	AND/OR	Over-The Counter Use____ (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 K083734