MAY - 9 2008

Xoft

K072616

510(k) Summary

Submitter

Xoft, Inc.
49000 Milmont Dr
Fremont, CA 94538
Contact Name: Eric Hashemian
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Summary was prepared on September 13, 2007

Name of Device

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

Predicate Device

Device Name	Premarket Notification
Varian Intracavitary Brachytherapy Applicators Vaginal Applicator Set #11-00414	K033371

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Device Description

The Axxent Vaginal Applicator is a component of the Axxent Electronic Brachytherapy System which utilizes a proprietary miniature X-ray source and does not require radioactive isotopes. Each applicator provides a channel for the Axxent HDR X-ray Source-2.2 to deliver high-dose rate, low energy radiation treatment. The source mimics the penetration and dose characteristics of Iridium 192 within the target volume. The Axxent Vaginal Applicators are available in 4 different sizes. The applicators are reusable and sterilizable. An Applicator Clamp and Base Plate are provided as a required accessory to stabilize the Vaginal Applicator during radiation treatment.

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 Vaginal Applicator are the same as the device approved in K033371. 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY - 9 2008

Mr. Eric Hashemian
Director of Regulatory Affairs
Xoft, Inc.
345 Potrero Avenue
SUNNYVALE CA 94085

Re: K072616
Trade/Device Name: Axxent® Vaginal Appicator Set
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: March 27, 2008
Received: March 31, 2008

Dear Mr. Hashemian:

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 (Premarket Approval), 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

Xoft, Inc.
Fremont, California

Indications for Use

510(k) Number: K072616

Device Name: Axxent® Vaginal Applicator

Indications for Use:

The Axxent Vaginal Applicator is indicated for use with the Axxent Electronic Brachytherapy System to deliver intracavitary brachytherapy in the vagina and rectum.

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 K072616