JUL 16 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 prepared on March 24, 2009

Name of Device

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

Predicate Device

Device Name	Premarket Notification
Xoft Axxent Balloon Applicator	K050843

Device Description

Note: No device design changes. The purpose of this submission is only to expand the indications for use of the Axxent Balloon Applicator to deliver intracavitary or intraoperative brachytherapy wherever the physician chooses to deliver radiation treatment.

The Axxent Balloon 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 intracavitary or intraoperative brachytherapy wherever the physician chooses to deliver radiation treatment.

The Axxent HDR X-ray Source mimics the penetration and dose characteristics of Iridium-192 within the treatment target. The Axxent Balloon Applicator is provided in five sizes to ensure proper fit into treatment areas of varying shapes and sizes. The applicators are disposable and provided sterile.

Intended Use

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

Summary of the Technological Characteristics

No device design changes. The technological characteristics of the Axxent Balloon Applicator are the same as the Axxent Balloon Applicator approved under K050843. 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

JUL 16 2009

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

Re: K090914
Trade/Device Name: Axxent® Balloon Applicator
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: June 18, 2009
Received: June 18, 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings device's labeling:

The Safety and effectiveness of the Axxent Electronic Brachytherapy System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-3150. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090914

Device Name: Axxent® Balloon Applicator

Indications for Use:

The Axxent Balloon Applicator is indicated for use with the Axxent Electronic Brachytherapy System to deliver intracavity or intraoperative brachytherapy wherever the physician chooses to deliver radiation treatment.

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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090914