

DEC 22 2005

Xoft, Inc.
Fremont, California
Premarket Notification
March 31, 2005

II. 510(k) Summary

K050843

A. Name of Device

Trade name: Axxent™ Electronic Brachytherapy System
Common name: X-Ray Radiation Therapy System
Classification name: X-Ray Radiation Therapy System and Accessories
(21 CFR 892.5900)

B. Predicate devices

Device Name	Premarket Notification (Date)
Photoelectron Corporation Photon Radiosurgery System (PRS) and Spherical Applicators	K992577 (09/23/1999)
Varian VariSource Remote Afterloader	K945383 (02/15/1995)
Proxima Therapeutics MammoSite Radiation Therapy System (RTS)	K011690 (05/06/2002)
Proxima Therapeutics MammoSite Radiation Therapy System (RTS)	K030558 (05/21/2003)
Proxima Therapeutics MammoSite Radiation Therapy System (RTS)	K032067 (02/10/2004)

C. Device description

The three components of the Axxent Electronic Brachytherapy System include the Controller, Balloon Applicators-BR and X-ray Source.

The Controller is a mobile platform that is responsible for the overall operation of the device. The radiation is delivered by a disposable, micro-miniature X-ray source located at the end of a flexible cable. The X-ray source at the distal tip of the cable is inserted into the central lumen of the appropriately-sized Balloon Applicator. The System is designed to deliver doses of X-ray radiation directly to the excised tumor bed when the physician desires to deliver intracavitary or interstitial radiation to the surgical margins following lumpectomy for breast cancer.

The Axxent Electronic Brachytherapy System does not utilize a radioactive isotope, or require an HDR isotope afterloader, and thus does not require the

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heavily-shielded treatment rooms necessary for the delivery of isotope-based HDR brachytherapy.

D. Intended use

The Xoft Axxent Electronic Brachytherapy System is intended to provide brachytherapy when the physician chooses to deliver intracavitary or interstitial radiation to the surgical margins following lumpectomy for breast cancer.

E. Technological characteristics

The technological characteristics of the Axxent Electronic Brachytherapy System are very similar to those of the predicate devices. These devices are equivalent in terms of design, materials, principles of operation, product specifications and sterilization.

F. Summary

The Axxent Controller has the same operating features as the VariSource afterloader in that both are software-controlled devices that control the placement and delivery of high dose rate brachytherapy sources. The Axxent Balloon Applicator-BR is substantially equivalent to the RTS devices in design, materials and intended use. The Axxent HDR X-ray Source 2.2 is substantially equivalent to the PRS Source in that the fundamental characteristics of the two devices are the same; they both generate x-rays of up to 50 keV energy for radiation therapy inside the body using similar technology and materials.

Thus by virtue of design, materials, function and intended use, the Axxent Electronic Brachytherapy System is substantially equivalent to devices legally marketed in the United States.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kathy O'Shaughnessy, Ph.D.
Vice President, Regulatory/Clinical/QA
Xoft, Inc.
49000 Milmont Drive
FREMONT CA 94538

Re: K050843
Trade/Device Name: Axxent Electronic Brachytherapy System
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: December 2, 2005
Received: December 5, 2005

Dear Dr. O'Shaughnessy:

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 section of the 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.

The warning must be presented within a black box, and the font should be bold and the same size as any surrounding text. The warning should be the first item in your list of warning.

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.

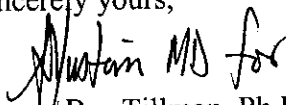
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification 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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). 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) 443-6597 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): K050843

Device Name: Axxent Electronic Brachytherapy System

FDA Indications For Use:

The Xoft Axxent Electronic Brachytherapy System is intended to provide brachytherapy when the physician chooses to deliver intracavitary or interstitial radiation to the surgical margins following lumpectomy for breast cancer.

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.

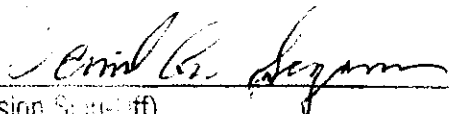
Prescription Use
(Part 21 CFR 801 Subpart D)

AND

Over-The-Counter Use _____
(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 Staff)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K050843

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