FEB 2 9 2008

510(k) Summary

K072683

Submitter

Xoft, Inc.
49000 Milmont Dr
Fremont, CA 94538
Contact Name: Eric Hashemian
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Summary was prepared on September 19, 2007.

Name of Device

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

Predicate Devices

Device Name	Premarket Notification
Axxent® Electronic Brachytherapy System (for Technological Characteristics)	K050843
Varian VariSource 200 HDR Afterloader (Indications for Use only)	K061582

Device Description

The Axxent Electronic Brachytherapy System (System) consists of three primary components: the Axxent System Controller (Controller); the Axxent HDR X-ray Source-2.2 (Source); and an Axxent-compatible applicator (Applicator). The System is designed to deliver doses of X-ray radiation to the tissue in proximity to the applicator using a disposable, miniature X-ray tube powered by the Controller.

The Axxent Electronic Brachytherapy Controller is a mobile, computer-controlled platform that is responsible for the overall operation of the System. The Controller is designed to work with the Source, which is a disposable, miniature X-ray tube located at the end of a flexible cable. The Source is inserted into a lumen of the appropriate Applicator.

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 Electronic Brachytherapy System are the same as the Axxent Electronic Brachytherapy System cleared in K050843. These devices are equivalent in terms of design, materials, principles of operation and product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 29 2008

Mr. Eric Hashemian
Director of Regulatory Affairs
Xoft, Incorporated
49000 Milmont Drive
FREEMONT CA 94538

Re: K072683
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: January 21, 2008
Received: January 25, 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). 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 warnings. The safety and effectiveness of this device for use as replacement for whole breast irradiation in the treatment of breast cancer have 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); 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 (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: K072683

Device Name: Axxent® Electronic Brachytherapy System

Indications for Use:

The Axxent® Electronic Brachytherapy System is a high dose rate Brachytherapy device for use with Axxent Applicators to treat lesions, tumors and conditions in or on the body where radiation is indicated.

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072683