Section 2: 510(k) Summary

JUN 2 6 2013

510(k) SUMMARY
(per 21 CFR §807.92)

INTRABEAM® Flat Applicator and INTRABEAM® Surface Applicator used with the INTRABEAM® System

General Information

Manufacturer:	Carl Zeiss Meditec AG Location: Oberkochen Carl-Zeiss-Strasse 22 73447 Oberkochen, Germany Est. Reg. No. 9615010
Contact Person:	Sarah Harrington, MS, MBA Staff Regulatory Specialist Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 Phone: (925) 560-5134 FAX: (925) 557-4259 Email: sarah.harrington@zeiss.com

Device Name/Classification

Trade/Proprietary name:	INTRABEAM® Flat Applicator used with the INTRABEAM® System INTRABEAM® Surface Applicator used with the INTRABEAM® System
Common/Usual Name:	X-ray radiation therapy system
Classification name:	System, Therapeutic, X-ray
Classification:	Class II (21 CFR 892.5900)
Product Code:	JAD

Predicate Device

Company:	Xoft, Inc.
Device:	Axxent® Surface Applicator, K083734

Intended Use for INTRABEAM Flat Applicator and INTRABEAM Surface Applicator

The INTRABEAM® System is a system for radiotherapy treatment.

Indications for Use: INTRABEAM Flat Applicator

The INTRABEAM® Flat Applicator is intended to supply a specified radiation dose during applications exclusively in combination with the INTRABEAM System.

- During intraoperative radiotherapy, on a surgically exposed surface or in a tumor bed.
- During treatment of tumors on the body surface.

The INTRABEAM® Flat Applicator is designed to deliver a flat radiation field at a distance of 5 mm from its circular application surface in water.

Indications for Use: INTRABEAM Surface Applicator

The INTRABEAM® Surface Applicator is intended to supply a specified radiation dose during applications exclusively in combination with the INTRABEAM System.

- During intraoperative radiotherapy, on a surgically exposed surface or in a tumor bed.
- During treatment of tumors on the body surface.

The INTRABEAM® Surface Applicator is designed to deliver a flat radiation field directly at the applicator's surface.

Device Description

The INTRABEAM System is a miniature, high-dose rate, low energy X-ray source that emits X-ray radiation intraoperatively for the treatment of cancer at the tumor cavity. The INTRABEAM Flat Applicator and INTRABEAM Surface Applicator are accessories to the INTRABEAM System that have been developed to provide radiotherapy to cancer lesions at or near the tissue surface. There are six sizes of INTRABEAM Flat Applicators in a set. The sizes are 1.0 cm, 2.0 cm, 3.0 cm, 4.0 cm, 5.0 cm and 6.0 cm in diameter. The INTRABEAM Surface Applicators are available in the four sizes. These sizes are 1.0 cm, 2.0 cm, 3.0 cm and 4.0 cm. The four smaller sizes of INTRABEAM Flat Applicators (size 1.0 to 4.0 cm) have the same dimensions and appearance as the INTRABEAM Surface Applicators (sizes 1.0 to 4.0 cm).

The INTRABEAM System has a maximum voltage of 50 kV and a maximum current of 40 µA. The INTRABEAM Flat Applicator and the INTRABEAM Surface Applicator provide a uniform dose of radiotherapy distributed across a flat surface. The applicators are made from the same materials. From a technical point of view, the INTRABEAM Flat and Surface Applicators are basically the same, but are optimized for treating different tissue depths.

Substantial Equivalence

The predicate device is the Axxent Surface Applicator (K083734) manufactured by Xoft, Inc. The Axxent Surface Applicator is indicated for use with the Axxent Electronic Brachytherapy System to deliver surface brachytherapy and Intraoperative Radiation Therapy (IORT) during the time the treatment site is exposed surgically. The device delivers 50 kVp x-ray radiation to shallow tissue depths over small targeted areas. The Axxent Surface Applicator is similar to the INTRABEAM Flat Applicator and INTRABEAM Surface Applicator in target site, clinical use, principles of operation and indications for use.

Summary

The INTRABEAM Flat Applicator and INTRABEAM Surface Applicator are equivalent to the currently marketed Axxent Surface Applicator in design, principle of operation and application. Based on the information provided in the 510(k) and the comparison to the currently marketed predicate, the INTRABEAM Flat Applicator and INTRABEAM Surface Applicator are safe and effective with regards to the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Carl Zeiss Meditec, Inc.
% Sarah Harrington, MS, MBA
Staff Regulatory Specialist
5160 Hacienda Drive
DUBLIN CA 94568

June 26, 2013

Re: K130549
Trade/Device Name: INTRABEAM Flat Applicator & INTRABEAM Surface Applicator
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: May 16, 2013
Received: May 17, 2013

Dear Ms. Harrington:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130549

Device Name: INTRABEAM® Surface Applicator used with INTRABEAM® System

Indications for Use:

The INTRABEAM® Surface Applicator is intended to supply a specified radiation dose during applications exclusively in combination with the INTRABEAM System.

- During intraoperative radiotherapy, on a surgically exposed surface or in a tumor bed.
- During treatment of tumors on the body surface.

The INTRABEAM® Surface Applicator is designed to deliver a flat radiation field directly at the applicator's surface.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

Michael O. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130549