K051055

510(k) Summary
Carl Zeiss Surgical GmbH
INTRABEAM® System

MAY 2 3 2005

1. SPONSOR

Carl Zeiss Surgical GmbH
Carl Zeiss Strasse 4-54
D-73446 Oberkochen
Germany

Contact Person: Michael Haisch, Director, Quality Management
Telephone: +49-7364-20-2555

Date Prepared: April 20, 2005

2. DEVICE NAME

Proprietary Name: INTRABEAM® System
Common/Usual Name: X-Ray Radiation Therapy Control Unit
Classification Name: X-ray Radiation Therapy Systems and Accessories

3. PREDICATE DEVICES

PRS400 System (*K980526 and K992577*)

4. DEVICE DESCRIPTION

The INTRABEAM® System described in this Special 510(k) is a modification and enhancement of the PRS400 System cleared under K980526 and K992577. The INTRABEAM® System consists of the PRS500 Control Console, the XRS 4, the Workstation Software, the User Terminal, the verification accessories, and the treatment accessories. The PRS500 Control Console provides all low-level operational control and safety functions of this System. The User Terminal with Workstation Software is the primary interface between the System and the user. The Software provides the high level control and display functions of the System. With the INTRABEAM® System, the radiologist, physicist, or technologist uses the Workstation Software on the User Terminal to set up the PRS500 Control Console (*perform the pre-treatment verification and treatment planning*), perform the treatment to completion, log all procedure variables and events, and after completion of the treatment, save and/or print treatment and performance data.

5. INTENDED USE

The INTRABEAM® System is intended to be used for radiation therapy treatment.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Equivalence of the INTRABEAM® System with the PRS 400 System is based on intended use, indications for use, technological characteristics, system specifications, and operational characteristics.

7. TESTING

The INTRABEAM® System was systematically tested to demonstrate that the modifications did not adversely affect safety and effectiveness. Testing described in this premarket notification included functionality (*integration testing of hardware, firmware, and accessories*), safety, electrical safety, electromagnetic compatibility, environmental testing, mechanical stress testing, and validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carl Zeiss Surgical GmbH
c/o Rosina Robinson, RN, MEd, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

MAY 2 3 2005

Re: K051055
Trade/Device Name: Carl Zeiss Surgical GmbH INTRABEAM® System
Regulation Number: 21 CFR §892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: April 25, 2005
Received: April 26, 2005

Dear Ms. Robinson:

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 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" (21 CFR 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,

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

510(k) Number (if known): K051055

Device Name: Carl Zeiss Surgical GmbH INTRABEAM® System

Indications for Use:

The INTRABEAM® System is indicated for radiation therapy treatments. The INTRABEAM® Spherical Applicators are indicated for use with the INTRABEAM® System to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity or intraoperative radiotherapy treatments.

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 NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051055