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

December 15, 2016

Carl Zeiss Meditec AG
% Calley Herzog
Senior Consultant
Biologics Consulting
400 N. Washington St. Suite 100
ALEXANDRIA VA 22314

Re: K162568
Trade/Device Name: INTRABEAM 600
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: December 5, 2016
Received: December 6, 2016

Dear Calley Herzog:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162568

Device Name

INTRABEAM 600

Indications for Use *(Describe)*

The INTRABEAM 600 is indicated for radiation therapy treatments.
The INTRABEAM Spherical Applicators are indicated for use with the INTRABEAM 600 to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments.
The INTRABEAM Spherical Applicators used with the INTRABEAM 600 are able to deliver a prescribed dose of intraoperative radiation in conjunction with whole breast irradiation, based upon the medical judgment of the physician. The safety and effectiveness of the INTRABEAM 600 as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.
The Needle Applicator set (comprising the Needle Applicator and guide shafts) is intended for use in combination with the INTRABEAM 600 to intraoperatively administer radiation to tissue including irradiation of intracranial tumors.
The INTRABEAM Flat Applicator is intended to supply a specified radiation dose during applications in combination with the INTRABEAM 600,
• 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 5mm from its circular application surface in water.
The INTRABEAM Surface Applicator is intended to supply a specified radiation dose during applications in combination with the INTRABEAM 600.
• 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the INTRABEAM 600 is provided below.

Device Common Name:	Therapeutic X-ray System
Device Trade Name:	INTRABEAM 600
Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena Germany
Contact:	Dr. Christian Muenster Director Regulatory and Clinical Affairs +49 7364 206985 christian.muenster@zeiss.com
Prepared by:	Calley Herzog Biologics Consulting Group cherzog@biologicsconsulting.com Phone: 720-883-3633
Date Prepared:	**November 22, 2016**
Classification Regulation:	21 CFR 892.5900, Class II, X-ray radiation therapy system
Panel:	Radiology
Product Code:	JAD - Therapeutic X-ray System
Primary Predicate:	K051055 - INTRABEAM System
Additional Predicates:	K090584 – INTRABEAM System K110590 – INTRABEAM System w/ Needle Applicator K121653 – INTRABEAM System w/ Spherical Applicators K130549 – INTRABEAM System w/ Flat and Surface Applicators
Reference Predicate:	K153368 – Radiance V3

Indication for Use:

The INTRABEAM 600 is indicated for radiation therapy treatments.

The INTRABEAM Spherical Applicators are indicated for use with the INTRABEAM 600 to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments.

The INTRABEAM Spherical Applicators used with the INTRABEAM 600 are able to deliver a prescribed dose of intraoperative radiation in conjunction with whole breast irradiation, based upon the medical judgment of the physician. The safety and effectiveness of the INTRABEAM 600 as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

The Needle Applicator set (comprising the Needle Applicator and guide shafts) is intended for use in combination with the INTRABEAM 600 to intraoperatively administer radiation to tissue including irradiation of intracranial tumors.

The INTRABEAM Flat Applicator is intended to supply a specified radiation dose during applications in combination with the INTRABEAM 600,

- 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 5mm from its circular application surface in water.

The INTRABEAM Surface Applicator is intended to supply a specified radiation dose during applications in combination with the INTRABEAM 600.

- 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 600 is a radiation therapy device intended for targeted treatments of selected lesions for minimally invasive, intraoperative, interstitial, intracavity and contact radiation therapy of tumors or tumor beds within the body of cancer patients. By applying the radiation source in conjunction with various applicators, a prescribed dose of low energy radiation can be delivered to the target volume. The delivery of the radiation dose is controlled via the integrated control unit and software.

The INTRABEAM 600 is provided as a mobile workstation. Like the previously cleared versions of the INTRABEAM system, the INTRABEAM 600 provides several tools for Quality Assurance of radiation delivery, which are intended to verify the proper functioning of the radiotherapy treatment system.

The main components of the INTRABEAM 600 system are:

- INTRABEAM Workplace - mobile cart containing the following:
  - Control Console 600 (CC600)

  - Computer with Software Version 4.0
  - Touchscreen monitor, keyboard and mouse
  - Dosimeter (UNIDOS E)
  - V-guide
- XRS 4 X-ray Source
- Quality Assurance Tools: PAICH, PDA, and Ionization Chamber with Ionization Chamber Holder
- radiance - Third party treatment planning simulation software

The applicators used with the INTRABEAM 600 are identical to the applicators cleared in previous 510(k)s.

Performance Data:

Electrical Safety Testing

The INTRABEAM 600 was assessed for conformity with the relevant requirements of *IEC 60601-1: 2005+ A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* and was found to comply.

The INTRABEAM 600 was assessed for conformity with the relevant requirements of *IEC 60601-2-8: 2010+A1:2015 Medical electrical equipment Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV* and was found to comply.

The INTRABEAM 600 was assessed for conformity with the relevant requirements of *IEC 60601-1-6: 2010 + A1:2013 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability* and was found to comply.

Electromagnetic Compatibility Testing

The INTRABEAM 600 was assessed for conformity with the relevant requirements of *IEC 60601-1-2: Ed. 3 / 2007Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests* and was found to comply.

System Level Verification

The system level testing verified that the device performed according to requirements.

Safety of Therapeutic X-Ray

The INTRABEAM was tested and shown to comply with the requirements of *IEC 60601-2-8:2010+A1:2015 Medical electrical equipment Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*. The INTRABEAM 600 passed all tests.

Environmental Testing

The system performed according to requirements under the expected conditions of use.

DICOM Conformity Assessment

The DICOM Conformance Statement was provided.

Software Verification and Validation

Software documentation was provided in accordance with FDA's software guidance documents. The results of verification and validation testing demonstrate that the software performs in accordance with its established requirements and will therefore meet user needs and intended uses.

Device Comparison Table:

Item	**Proposed Device INTRABEAM 600**	**Predicate Device INTRABEAM System (K051055)**	**SE Assessment**
Device Name	INTRABEAM 600	INTRABEAM System (INTRABEAM PRS 500 with XRS 4)	N/A
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	N/A
Regulation Name	X-ray radiation therapy system	X-ray radiation therapy system	Identical
Regulation	21 CFR 892.5900, Class II	21 CFR 892.5900, Class II	Identical
Product Code	JAD: System, Therapeutic, X-Ray	JAD: System, Therapeutic, X-Ray	Identical
Use Environment	Operating room or practitioner's office	Operating room or practitioner's office	Identical
System Component Storage Cart	INTRABEAM Workplace – a fully enclosed cart that provides dedicated storage space for each component secured inside the cart	Components were provided with a cart for storage and transportation	Similar
System Components on Cart	Control Console 600 (CC600)	Control Console PRS 500	Similar
	Computer, Touchscreen Monitor, Keyboard, Mouse	INTRABEAM User Terminal (keyboard with touchpad, mouse)	Similar
	UNIDOS E (Dosimeter)	UNIDOS E (Dosimeter)	Identical
	Ionization Chamber	Ionization Chamber	Identical
	V-guide	X-Block and V-Block guide	Similar
Method of treatment / application	Intraoperative Intracavitary Interstitial Post-Operative	Intraoperative Intracavitary Interstitial Post-Operative	Identical
Radiation Source	XRS 4	XRS 4	Identical

Item	Proposed Device INTRABEAM 600	Predicate Device INTRABEAM System (K051055)	SE Assessment
General mode of operation of the X-Ray source	Electrons are emitted by cathode, accelerated by an electrical field along a drift tube inside the X-Ray source and hit a gold target resulting in the generation of X-rays	Electrons are emitted by cathode, accelerated by an electrical field along a drift tube inside the X-Rays source and hit a gold target resulting in the generation of X-rays.	Identical
Maximum radiation output	0.6Gy/min (at 2cm from isocenter)	0.6Gy/min (at 2cm from isocenter)	Identical
Maximum photon energy	50keV	50keV	Identical
Geometry of dose emitted (without applicator)	Mostly spherical	Mostly spherical	Identical
Dose fall-off (in water)	~$1/r^3$	~$1/r^3$	Identical
Maximum Power Range	2W (50kV x 40µA)	2W (50kV x 40µA)	Identical
Maximum Beam Current	40µA	40µA	Identical
System Quality Assurance (SQA) Tools	Probe Adjuster Ionization Chamber Holder (PAICH) Photo Diode Array (PDA) Ionization Chamber (IC)	Probe Adjuster Ionization Chamber Holder (PAICH) Photo Diode Array (PDA) Ionization Chamber (IC)	Identical
Radiation Treatment Planning Software	Radiance (K153368)	None	New feature for subject device – it is compatible with previously cleared third party software.
Compatible Applicators	INTRABEAM Spherical Applicators INTRABEAM Flat Applicator Set (K130549) INTRABEAM Surface Applicator Set (K130549) INTRABEAM Needle Applicator (K110590)	INTRABEAM Spherical Applicators	Similar – the subject device is compatible with the listed previously cleared applicators. No changes made to the applicators.

Substantial Equivalence Summary:

Based on the comparison of intended use, indications for use and technological characteristics, the subject device is similar to the predicate device. Any differences between the devices was shown to be equivalent with performance, safety and software testing. Therefore, the INTRABEAM 600 can be found substantially equivalent to the predicate device as cleared in K051055.