Carl Zeiss Meditec AG
Chaitali Gawde
Senior Regulatory Affairs Specialist
Carl Zeiss Meditec, Inc.
5300 Central Parkway
Dublin, California 94588

January 10, 2025

Re: K241174
Trade/Device Name: INTRABEAM (700); And accessories (INTRABEAM SMART Stand, INTRABEAM SMART Spherical Applicator, INTRABEAM Spherical Sizer Set, INTRABEAM Needle Applicator)
Regulation Number: 21 CFR 892.5900
Regulation Name: X-Ray Radiation Therapy System
Regulatory Class: Class II
Product Code: JAD
Dated: April 26, 2024
Received: December 13, 2024

Dear Chaitali Gawde:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241174

Device Name
INTRABEAM (700);
And accessories (INTRABEAM SMART Stand, INTRABEAM SMART Spherical Applicator, INTRABEAM Spherical Sizer Set, INTRABEAM Needle Applicator)

Indications for Use *(Describe)*
The INTRABEAM is intended for use in radiotherapy treatments.

The INTRABEAM SMART Spherical Applicator is used with the INTRABEAM to deliver a prescribed dose of intraoperative radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments.

The safety and effectiveness of the INTRABEAM as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

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

The INTRABEAM SMART Stand is designed as an instrument support and positioning unit for the INTRABEAM.

The INTRABEAM Spherical Sizer Set shall support the doctor (surgeon and/or radiation oncologist) in assessing which spherical-shaped applicator shall be used for the radiation therapy procedure, involving INTRABEAM.

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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In accordance with 21 CFR 807.92 the K241174 510(k) Summary for the INTRABEAM (Model No: 700), and accessories (INTRABEAM SMART Stand, INTRABEAM SMART Spherical Applicator, INTRABEAM Spherical Sizer Set, and INTRABEAM Needle Applicator) is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec AG Rudolf-Eber-Strasse 11 73447 Oberkochen Germany
Applicant Contact Name	Anke Seitz Head of Regulatory and Clinical Affairs Innovation MCS Rudolf- Eber- Str. 11 Oberkochen, Germany 73447 +49 7364 20 8613 Phone E-mail: anke.seitz@zeiss.com (preferred)
Primary Correspondent	Chaitali Gawde Senior Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 (224) 300-3992 Phone E-mail: chaitali.gawde@zeiss.com (preferred)
Secondary Correspondent	Paul Swift Head of Regulatory and Clinical Affairs, Americas Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 (817) 925.8507 Phone E-mail: paul.swift@zeiss.com (preferred)
Date Prepared:	January 09, 2025

2. DEVICE

Device Trade Name:	INTRABEAM (Model No: 700), and accessories (INTRABEAM SMART Stand, INTRABEAM SMART Spherical Applicator, INTRABEAM Spherical Sizer Set, and INTRABEAM Needle Applicator)
Classification:	21 CFR 892.5900 X-ray radiation therapy system
Regulatory Class:	II
Product Code:	JAD

3. LEGAL MARKETED PREDICATE DEVICE

Predicate Device Name:	INTRABEAM 600 (K162568)
Classification:	21 CFR 892.5900 X-ray radiation therapy system
Regulatory Class:	II
Product Code:	JAD

4. DEVICE DESCRIPTION SUMMARY

The INTRABEAM 700 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 700 is provided as a mobile workstation. Like the previously cleared versions of the INTRABEAM system, the INTRABEAM 700 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 700 system are:

- INTRABEAM Workplace - mobile cart containing the following:
  - Control Console 700 (CC700)
  - Computer with Software Version 5.0
  - Touchscreen monitor and mouse
  - UNIDOS Romeo Electrometer
  - 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 INTRABEAM SMART Stand is connected to the INTRABEAM 700 and is used to mount the X-ray generator (XRS 4) and the necessary applicator, in order to deliver the prescribed radiation dose at the target site.

The INTRABEAM Spherical Applicator is a sterile disposable product that shall be placed in contact with the tumor mass and/or tumor resection cavity to deliver a prescribed dose of intraoperative radiation.

The INTRABEAM Spherical Sizer Set is a sterile disposable product that shall be placed in contact with body part and/or tumor mass to help support the doctor (surgeon and/or radiation oncologist) in assessing which spherical-shaped applicator shall be used for the radiation therapy procedure, involving INTRABEAM.

The INTRABEAM Needle Applicator has not been updated since the last clearance, K162568.

5. INTENDED USE/INDICATIONS FOR USE

The INTRABEAM is intended for use in radiotherapy treatments.

The INTRABEAM SMART Spherical Applicator is used with the INTRABEAM to deliver a prescribed dose of intraoperative radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments.

The safety and effectiveness of the INTRABEAM as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

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

The INTRABEAM SMART Stand is designed as an instrument support and positioning unit for the INTRABEAM.

The INTRABEAM Spherical Sizer Set shall support the doctor (surgeon and/or radiation oncologist) in assessing which spherical-shaped applicator shall be used for the radiation therapy procedure, involving INTRABEAM.

6. SUBSTANTIAL EQUIVALENCE

Table 1. Subject to Predicate Device Comparison Table – Indications for Use

Item	Subject Device INTRABEAM (K241174)	Predicate Device INTRABEAM 600 (K162568)	Substantial Equivalence Assessment
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	21 CFR 892.5900	Identical
Device Class	Class II	Class II	Identical
Product Code	JAD	JAD	Identical
Classification Name	System, Therapeutic, X-Ray	System, Therapeutic, X-Ray	Identical
Use Environment	Operating room or practitioner's office	Operating room or practitioner's office	Identical
Indications for Use	The INTRABEAM is intended for use in radiotherapy treatments. The INTRABEAM SMART Spherical Applicator is used with the INTRABEAM to deliver a prescribed dose of intraoperative	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	Equivalent – new accessories were added

Item	Subject Device INTRABEAM (K241174)	Predicate Device INTRABEAM 600 (K162568)	Substantial Equivalence Assessment
	radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments. The safety and effectiveness of the INTRABEAM as a replacement for whole breast irradiation in the treatment of breast cancer has not been established. The INTRABEAM Needle Applicator (comprising the Needle Applicator and guide shafts) is intended for use in combination with the INTRABEAM to intraoperatively administer radiation to tissue including irradiation of intracranial tumors.	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	

Item	Subject Device INTRABEAM (K241174)	Predicate Device INTRABEAM 600 (K162568)	Substantial Equivalence Assessment
		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.	
	The INTRABEAM SMART Stand is designed as an instrument support and positioning unit for the INTRABEAM. The INTRABEAM Spherical Sizer Set shall support the doctor (surgeon and/or radiation oncologist) in assessing which spherical-shaped applicator shall be used for the radiation therapy procedure, involving INTRABEAM.		

Table 2. Subject to Predicate Device Comparison Table – INTRABEAM main device

Item	Subject Device INTRABEAM (Model: 700) (K241174)	Predicate Device INTRABEAM 600 (K162568)	Substantial Equivalence Assessment
Device Name	INTRABEAM 700	INTRABEAM 600	N/A
System Component Storage Cart	INTRABEAM Workplace – a fully enclosed cart that provides dedicated storage space for each component secured inside the cart	INTRABEAM Workplace – a fully enclosed cart that provides dedicated storage space for each component secured inside the cart	Identical
System Components on Cart	Control Console 700 (CC700)	Control Console 600 (CC600)	Equivalent- subject device makes use of a different power supply concept. Safety is proven by established methods

Item	Subject Device INTRABEAM (Model: 700) (K241174)	Predicate Device INTRABEAM 600 (K162568)	Substantial Equivalence Assessment
			IEC 60601-1 and IEC 60601-2-8
	Computer, Touchscreen Monitor, Mouse, (Keyboard functionality is available via the touchpad)	Computer, Touchscreen Monitor, Keyboard, Mouse	Identical
	UNIDOS Romeo Electrometer	UNIDOS E (Dosimeter)	Equivalent – UNIDOS Romeo Electrometer is the successor model and cleared under (K951764)
	Ionization Chamber	Ionization Chamber	Identical
	V-guide	V-guide	Identical
Radio Modules	RFID Reader	N/A	Equivalent - RFID reader will not have an impact on the use of the device.
Network	Wireless or LAN	LAN	Equivalent - used for connection of PC with hospital network
Connectivity	– Picture Archiving and Communication System (PACS) – ZEISS SMART Service – ZEISS Server / Cloud - Health Data Platform (HDP)	– Picture Archiving and Communication System (PACS)	Equivalent – additional connectivity features in the subject device, no impact on the intended use of the device.
Applicators required for Treatment	Yes	Yes	Identical
Method of treatment / application	Intraoperative Intracavitary Interstitial Post-Operative	Intraoperative Intracavitary Interstitial Post-Operative	Identical
Radiation Source	XRS 4	XRS 4	Identical
Software on Computer	Version 5.0	Version 4.0	Equivalent – Updated Software Version
Controller Set	40keV 50keV	40keV 50keV	Identical
Energy range used	40keV 50keV	40keV 50keV	Identical
Energy of radiation emitted	Max 50keV	Max 50keV	Identical

Item	Subject Device INTRABEAM (Model: 700) (K241174)	Predicate Device INTRABEAM 600 (K162568)	Substantial Equivalence 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-Ray 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
Does 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 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 V5	Radiance V4	Equivalent – Radiance 4 (K171885) Radiance 5 (K233236)
Compatible Applicators	– INTRABEAM SMART Spherical Applicator (K241174) – INTRABEAM Needle Applicator (K110590)	– INTRABEAM Spherical Applicator (K121653) – INTRABEAM Flat Applicator Set (K130549) – INTRABEAM Surface Applicator Set (K130549) – INTRABEAM Needle Applicator (K110590)	Equivalent – new compatible applicator is introduced for INTRABEAM 700
Stand	INTRABEAM SMART Stand: - Wireless Module - RFID Module with auto-draping functionality - auto-balancing - active vibration damping & application modes	NC32 INTRABEAM Floor Stand	Equivalent - SMART Stand offers more functions for INTRABEAM 700

Table 3. Subject to Predicate Device Comparison Table – INTRABEAM SMART Spherical Applicator

Item	**Subject Device INTRABEAM SMART Spherical Applicator (K241174)**	**Predicate Device INTRABEAM Spherical Applicator (K121653)**	**Substantial Equivalence Assessment**
Device Name	INTRABEAM SMART Spherical Applicator	INTRABEAM Spherical Applicator	N/A
Energy source	X-ray source	X-ray source	Identical
Maximum Voltage (kV)	50 kV or 40 kV	50 kV or 40 kV	Identical
Maximum Current (µA)	40 µA	40 µA	Identical
Number of applicator sizes	Eight (8)	Eight (8)	Identical
Applicator Diameters	Spherical Diameter: 1.5 cm; 2 cm; 2.5 cm; 3 cm; 3.5 cm; 4 cm; 4.5 cm and 5 cm	Spherical Diameter: 1.5 cm; 2 cm; 2.5 cm; 3 cm; 3.5 cm; 4 cm; 4.5 cm and 5 cm	Identical
Materials	Sphere: Polyetherimide Shaft: Polyetherimide	Sphere: Polyetherimide (Ultem 1000) Shaft: Ultem 1000 and stainless steel	Equivalent – Stainless steel no longer used, does not affect the intended use of the device.
Sterilization	Supplied sterile; EO Sterilization	Supplied non-sterile. User performs steam sterilization.	Equivalent – sterilization is carried out in both.
Number of uses	Single-Use	Multiple uses. Can be sterilized 100 times by the user.	Equivalent – there is no impact on the use of the device.
Primary Packaging	Lid: Tyvek® Blister: PETG transparent	N/A	Equivalent – Primary packaging was not required before, as device was sterilized by the user.
Connectivity	RFID tag	N/A	Equivalent - RFID tag will not have an impact on the use of the device.
Sizing support tool	INTRABEAM Spherical Sizer Set - Gamma sterilization - Single-Use - 8 different sizes - Base Material: polycarbonate - Color Batch Material: Acrylnitril-Butadien-Styrol	N/A	Equivalent – INTRABEAM Spherical Sizer Set will support the user to pick appropriate INTRABEAM SMART Spherical Applicator

Item	Subject Device INTRABEAM SMART Spherical Applicator (K241174)	Predicate Device INTRABEAM Spherical Applicator (K121653)	Substantial Equivalence Assessment
	- Primary Packaging: Tyvek® and laminate film transparent peel PET-O/PP		

7. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY OF STUDIES

Sterilization and Shelf Life

The INTRABEAM was assessed for Sterility and Shelf-life information per recommendations in FDA's Sterility guidance document and were deemed to demonstrate substantial equivalence.

Biocompatibility

The device consists of patient-contacting materials; therefore, a biocompatibility assessment was performed in accordance with FDA's biocompatibility guidance documents.

The biocompatibility evaluation demonstrated substantial equivalence.

Performance Testing – Bench

Non-clinical system testing provided an evaluation of the performance of the system relevant to each of the system specifications. The functional and system level testing showed that the system met the defined specifications. Software verification testing has been performed to demonstrate that software is performing as intended.

The following parameters/specifications were tested in conformity with the relevant requirements:

- EMC, Wireless, Electrical, Mechanical, and Thermal Safety

  The INTRABEAM (model no: 700) with INTRABEAM SMART Stand were assessed for conformity with the relevant requirements of IEC 60601-1-2 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests" and were found to comply.

  The INTRABEAM (model no: 700) with INTRABEAM SMART Stand were assessed for conformity with the relevant requirements of IEC TR 60601-4-2 "Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems" and were found to comply.

  The INTRABEAM (model no: 700) with INTRABEAM SMART Stand, INTRABEAM SMART Spherical Applicator and INTRABEAM Needle Applicator (as detachable parts) were assessed for conformity with the relevant requirements of IEC 60601-1 "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance" and were found to comply.

- Radiation Safety

  The therapeutic X-ray equipment of INTRABEAM (model no: 700) with INTRABEAM SMART Stand were assessed for conformity with the relevant requirements of IEC 60601-2-8 "Medical electrical equipment - Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV" and were found to comply.

- System Level Verification

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

- Software Verification and Validation

  Software documentation was provided in accordance with FDA's software guidance documents. Enhanced documentation was submitted for INTRABEAM (Model: 700) and its accessories. 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. Also, the FDA's cybersecurity recommendations were fulfilled.

- Usability / Human Factors

  The INTRABEAM (model no: 700) with INTRABEAM SMART Stand, INTRABEAM SMART Spherical Applicator and INTRABEAM Needle Applicator (as detachable parts) were assessed for conformity with the relevant requirements of IEC 60601-1-6 "Medical electrical equipment – Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability". And the FDA's recommendations for human factors validation are fulfilled.

All the performance testing evaluations demonstrated substantial equivalence.

8. CONCLUSION

The indications for use are equivalent to the indications for use of the predicate devices; and therefore, are deemed to demonstrate substantial equivalence.

The technological characteristics and risk profile of the subject device are equivalent to the predicate devices; and therefore, are deemed to demonstrate substantial equivalence.

Testing methods are equivalent to those of the predicate devices and support substantial equivalence.

Accordingly, the INTRABEAM (Model: 700 and accessories) is substantially equivalent to the predicate device, the INTRABEAM 600 (K162568).