December 3, 2025

Voxel Ray Solutions, LLC
Nicolas Soro
Director of Quality Assurance and Regulatory Affairs
200 Frontage Rd
Suite 200
Burr Ridge, Illinois 60527

Re: K250692
Trade/Device Name: GentleBeam
Regulation Number: 21 CFR 892.5900
Regulation Name: X-Ray Radiation Therapy System
Regulatory Class: Class II
Product Code: JAD
Dated: November 3, 2025
Received: November 3, 2025

Dear Nicolas Soro:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K250692

Device Name
GentleBeam

Indications for Use *(Describe)*
The GentleBeam is a low energy x-ray system, with imaging capability, intended for superficial radiotherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

The imaging capability, employed in a non-diagnostic mode, is used to assist the physician in the selection of the correct treatment area. The imaging component is a laser induced ultrasound scanning system used to visualize the layers of skin, including blood vessels, and to make approximate measurements of dimensions in layers of skin and blood vessels, by detecting laser pulse generated ultrasound waves.

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.**

# 510(k) Summary

[As Required by 21 CFR 807.92(c)]

**Submitter's Name & Address:** Voxel Ray Solutions, LLC
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Burr Ridge, IL 60527

**Contact Person:** Nicolas Soro
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**Date Summary Prepared:** November 1, 2025

**Device Name:** Trade/Proprietary Name – GentleBeam

Common/Usual Name – Superficial X-ray Radiation System with Imaging Capability

Classification Name – X-ray Radiation Therapy System (892.5900)

**Classification:** Class II

**Product Code:** JAD

**Regulation Number:** 892.5900

**Predicate Device:** K150037 SRT-100 Vision

## Device Description

The GentleBeam Radiation Therapy System is a mobile low-energy superficial radiotherapy device for treating skin cancer lesions and keloids. The X-ray source, delivers radiation emission in the low energy therapy ranges of 50kV, 70kV and 100 kV (a total of 3 energies) and is held in place by a manually guided robotic arm. The X-ray source uses single target collimators with a fixed SSD. The robotic arm is manually operated by the user and contains no automated functions, its sole purpose is to support the x-ray head and hold it steady so operator can deliver treatment to the patient. It does not move unless hand guided by the operator to position it. The imaging head produces an ultrasound image, generated using laser induced ultrasound (LIUS, branded as Photosonic) imaging technology for acquisition of internal structures of the skin.

The GentleBeam System includes the following major components:

- Preparation Console– Located on the base of the system to enter patient information, perform simulation and imaging.
- Treatment Console – Located outside the room to control radiation delivery.
- Robotic Arm – Holds the treatment head. Buttons on the robotic arm allows operator to position the arm precisely at the treatment site using hand-guided mode. No automated motions happen on the arm. All movement is through manual user movement.
- Treatment Head – Contains the x-ray source and collimated applicator for precise delivery of radiation treatment using a single focal spot. No multiple focal spots are on the applicators.
- Imaging Head – Ultrasound imaging unit for lesion depth measurement.
- Red Diode Positioning Laser - System uses a laser-pointing apparatus to assist the operator for a visual guide for positioning purposes of the x-ray source, located on the treatment head.
- Collimators/Applicators - Collimators (also called applicators) are used to collimate the X-ray beam output. The layout of each collimator consists of a single field and flattening filter, which is always used for treatment. The system contains the following applicators:
    - 50kV, 5cm SSD, 1.5cm/2cm/3cm/4cm/5cm diameter – single target
    - 70kV, 5cm SSD, 1.5cm/2cm/3cm/4cm/5cm diameter – single target
    - 100kV, 5cm SSD, 1.5cm/2cm/3cm/4cm/5cm diameter – single target
    - QC Applicator for daily quality assurance checks

**Technological Characteristics/Principles of Operation**

The GentleBeam System produces and emits filtered, low energy (50, 70, and 100 kV) x-ray radiation, which is electrically generated using the onboard High Voltage Power Supply (also referred to as HVPS).

The X-ray source consists of an electron acceleration stage. In general, kilovoltage x-ray sources produce x-rays by accelerating electrons onto a diamond-tungsten target, which is a high-Z material. The electrons decelerate in the target, and their energy is converted to x-ray radiation (referred to as Bremsstrahlung, literally "braking" radiation), which is emitted in a roughly isotropic radiation pattern.

The High Voltage power supply heats up the filament and generates up to 100kV in the X-Ray source. Later, the grid is turned off and electrons start moving from the cathode towards the anode, which in this case the anode is the target. Since the electron beam is affected by magnetic field created by the earth, the x-ray source includes deflection and focusing coils that apply a magnetic field to keep the electron beam directed at the aimed focal spot on the target. The "Bremsstrahlung" effect is takes place on the target and collimated x-rays are delivered to the patient.

To hold the x-ray source in place, the GentleBeam utilizes a robot arm which is intended to allow for the operator to hand-guide the x-ray source and provide a stable mount. The operator controls the robot in hand-guided mode to allow for full control of the robot, which does not operate in automated motion mode. This robot has been tested to and passed the ISO 13849 standard of safety for machinery, and in the IEC 60601-1 safety tests for medical devices.

The imaging head produces an ultrasound image, generated using laser induced ultrasound (LIUS, branded as Photosonic) imaging technology for acquisition of internal structures of the skin. The imaging system's primary function is to allow the operator to measure the lesion's depth and manually input the information into the GentleBeam software. The imaging system has been tested to IEC 60601-1 and IEC 60601-2-37.

**Indications for Use:**

The GentleBeam is a low energy x-ray system, with imaging capability, intended for superficial radiotherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

The imaging capability, employed in a non-diagnostic mode, is used to assist the physician in the selection of the correct treatment area. The imaging component is a laser induced ultrasound scanning system used to visualize the layers of skin, including blood vessels, and to make approximate measurements of dimensions in layers of skin and blood vessels, by detecting laser pulse generated ultrasound waves.

**Prescriptive Statement**

The GentleBeam system is intended for use by a qualified RTT and medical physicist.

Rx use only

Caution: Federal law restricts this device to sale by or on the order of a physician.

**Summary of Non-Clinical Performance Testing**

The GentleBeam System, as configured, has been engineered and tested to meet Voxel Ray Solutions, LLC product requirements, required electrical and mechanical safety standards, and meet clinical expectations. All testing of the GentleBeam was performed in accordance with defined test cases with clearly delineated acceptance criteria. The GentleBeam underwent a comprehensive bench, electrical/mechanical safety, EMC, software, usability, end-to-end, and performance verification/validation program. All testing met predefined acceptance criteria and supports that the device is as safe and effective as the predicate, with no new questions of safety or effectiveness.

Additionally, FDA consensus standards and recognized ISO and IEC standards (e.g., IEC 60601-1) were employed for the bench testing, functional testing, and overall system performance testing of the GentleBeam. Furthermore, all testing was commissioned to qualified and accredited independent laboratories.

Bench and performance testing (verification & validation):

- X-ray source/output physics verification: Independent, NIST-traceable ion-chamber measurements per AAPM TG-61 at 50/70/100 kV confirmed tube potential accuracy, HVL/beam quality, output rate, integrated output per exposure, timer accuracy, and surface dose tables.
- LIUS (laser-induced ultrasound) imaging characterization: Depth accuracy and axial/lateral resolution characterized using a calibrated multi-target phantom at varied depths/locations. Multiple scans per configuration were taken, as well as comparative scans against the predicate methodology included to confirm equivalent imaging utility for lesion depth measurement supporting treatment setup.
- System verification testing: Requirements-based V&V (≥200 tests) covering hardware, firmware, interlocks, alarms, user interface bounds, data logging, and error handling.
- System validation: Full system validation performed, including usability validation and end-to-end phantom exercises demonstrated that console settings and clinical setup yielded the expected field placement and delivered dose within predefined tolerances, with representative users.

- Usability engineering: Formative and summative evaluations per IEC 60601-1-6 / IEC 62366 for critical tasks (setup, parameter entry, SSD verification, exposure workflow, emergency stop).
- Electrical safety & EMC: Full testing to IEC 60601-1 and IEC 60601-1-2 (including immunity under worst-case operating modes). The system essential performance was maintained.
- Particular X-ray safety: Testing to IEC 60601-2-8 verified applicator integrity, beam on/off control, indicators, protection features, and essential performance.
- Ultrasound particular standard: Relevant safety/performance aspects of the LIUS module evaluated to IEC 60601-2-37 (scope limited to non-diagnostic imaging functions used to support treatment setup).

**Non-clinical Safety Tests**

The GentleBeam System has been designed and constructed to meet the following electrical and mechanical safety standards:

- IEC 60601-1 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- IEC 60601-1-6 Edition 3.2 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-8 Edition 2.1 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
- IEC 60601-2-37 Edition 2.1 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

- IEC 60825-1 Edition 2.0 Safety of laser products - Part 1: Equipment classification and requirements
- IEC 62366-1 Edition 1.1 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304 Edition 1.1 Medical device software - Software life cycle processes

**Substantial Equivalence Discussion**

| Attributes | Voxel Ray GentleBeam™ GB1000 | Predicate Device Sensus Healthcare SRT-100 Vision K150037 | Discussion |
|---|---|---|---|
| Intended Use | Superficial x-ray Radiation Therapy and electronic brachytherapy | Superficial x-ray Radiation Therapy and electronic brachytherapy | Equivalent |
| Indications for Use | The GentleBeam™ system is a low- energy X-ray system, with imaging capability, intended for superficial radiotherapy treatments of primary malignant epithelial neoplasms of the skin and keloids.<br><br>Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) metatypical carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.<br><br>The imaging capability, employed in a non- diagnostic mode, is used to assist the physician in the selection of the correct treatment area. The imaging component is a laser-induced ultrasound scanning system used to visualize the layers of skin, including blood vessels, and to make approximate | The SRT-100 Vision System is a low energy x-ray system, with ultrasound imaging capability, intended for superficial radiotherapy and electronic brachytherapy treatments of primary malignant epithelial neoplasms of the skin and keloids.<br><br>Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypical carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.<br><br>The ultrasound capability, employed in a non-diagnostic mode, is used to assist the physician in the selection of the correct cone applicator size. The Derma-Scan C Ultrasound component was initially cleared | Equivalent |

| Attributes | Voxel Ray GentleBeam™ GB1000 | Predicate Device Sensus Healthcare SRT-100 Vision K150037 | Discussion |
|---|---|---|---|
| | measurements of dimensions in layers of skin and blood vessels, by detecting laser pulse generated ultrasound waves. | with an indication for use as an ultrasonic scanning system used to visualize the layers of skin, including bold vessels, and to make approximate measurements of dimensions in layers of skin and blood vessels, by ultrasonic means.<br><br>The red-diode laser assembly is a commercial pointer device employed by physicians for improving the alignment of the focused beam | |
| Regulation Name | X-ray Radiation Therapy System | X-ray Radiation Therapy System | Equivalent |
| Regulation | 892.5900 | 892.5900 | Equivalent |
| Product Code | JAD | JAD | Equivalent |
| Use Environment | Operating room or practitioner's officer | Operating room or practitioner's office | Equivalent |
| Target Population | Not limited | Not limited | Equivalent |
| Device Type | Class II | Class II | Equivalent |
| Therapy Type | X-ray Photon | X-ray Photon | Equivalent |
| X-Ray Source Operation Mode | The X-ray source consists of a drift tube and electron acceleration stage. Once the electron beam hits the diamond-tungsten target, X-ray photons are generated primarily from the tungsten layer. The diamond layer dissipates the heat, and the collimator permits X-rays in the direction of the selected treatment area (field). | Electrons are emitted by cathode, accelerated by an electrical field along a drift tube inside the X-Ray source and hit a tungsten target resulting in the generation of X-rays | Equivalent |
| X-Ray Source Current | Voxel Ray<br>50 kV: 2.00 mA<br>70 kV: 2.86 mA<br>100 kV: 3.00 mA | Comet MXR-100<br>10 mA at 50kV<br>10 mA at 70 kV<br>8 mA at 100 kV | Similar. Comparison of technical equivalence below. |

| Attributes | Voxel Ray GentleBeam™ GB1000 | Predicate Device Sensus Healthcare SRT-100 Vision K150037 | Discussion |
|---|---|---|---|
| Geometry of Dose Emitted (without applicator) | Mostly Spherical | Mostly Spherical | Equivalent |
| Maximum Radiation Output | 500 - 1500 cGy/min | 400 – 1000 cGy/min (at 4cm – 3cm from isocenter, respectively) | Similar. Comparison of technical equivalence below. |
| High Voltage Input Range | 50-100 kV | 50 kV through 100 kV | Equivalent |
| Exposure | 0 to 3 minutes in 0.01 minute increments | 0 to 3 minutes in 0.01 minute increments | Equivalent |
| kV Control | Microprosessor | Microprocessor | Equivalent |
| Filters | 50 kV: 0.30 mm Al<br>70 kV: 0.70 mm Al<br>100 kV: 0.65 mm Al, 0.02 mm Cu | 0.10 mm Al at 20 to 40 kV<br>0.10 mm Cu at 50 to 100 kV<br>0.45 mm Al at 50kV<br>0.75 mm Al at 70 kV<br>1.15 mm Al at 100 kV<br>4.0 mm Al at 50 to100kV | Similar. Comparison of technical equivalence below. |
| mA Control | Microprocessor | Microprocessor | Equivalent |
| Primary Exposure Timer | Microprocessor | Microprocessor | Equivalent |
| Secondary (Backup) Exposure Timer | Yes- Microprocessor | Yes-Microprocessor | Equivalent |
| Timer Monitoring and Safety Shutoff | Yes-Hardware | Yes-Hardware | Equivalent |
| Safety Interlocks | Interlock to prevent unintended radiation<br>Interlock to prevent unintended access to the controlled area<br>Interlock to prevent incorrect radiation data transmission Robotic | Interlock to prevent unintended radiation Interlock to prevent unintended access to the controlled area Interlock to prevent incorrect radiation data transmission Robotic manipulator safety interlocks | Equivalent |

| Attributes | Voxel Ray GentleBeam™ GB1000 | Predicate Device Sensus Healthcare SRT-100 Vision K150037 | Discussion |
|---|---|---|---|
| | manipulator safety interlocks<br>Laser Interlock | | |
| Interlocked Filters | Yes | Yes | Equivalent |
| Output Power | 1000 W | 1000 W | Equivalent |
| X-ray Tube Target | Tungsten on diamond substrate (for heat dissipation). X-rays are produced by the tungsten target. | Tungsten. X-rays are produced by the tungsten target. | Equivalent |
| Focal Spot Size | 2 mm | 5.5mm | Similar. Comparison of technical equivalence below. |
| Radiation Beam Quality | 1.05mm Al @ 70kV<br>2.2mm Al @ 100kV | 1.1mm Al @ 70 kV<br>2.1mm Al @ 100 kV | Equivalent |
| X-ray Tube Cooling | Water and<br>Corrosion Inhibitor | Water | Equivalent |
| Mobility | Yes | Yes | Equivalent |
| Imaging Capability | Imaging System - Laser Induced generated Ultrasound (LIUS) | Cortex DermaScan C Ultrasound System component is integrated with the SRT-100 Vision computer and contains: (a) scanning main unit; (b) handheld probe and (c) a medical grade power supply to provide power to the computer. The ultrasound component is designed to meet international safety requirements | Similar. Comparison of technical equivalence below. |

| Attributes | Voxel Ray GentleBeam™ GB1000 | Predicate Device Sensus Healthcare SRT-100 Vision K150037 | Discussion |
|---|---|---|---|
| X-Ray Source Mounting Arm | 6-axis robotic manipulator mounted on the GentleBeam System's base. Load capacity of the robotic manipulator is < 16.4kg. Motion of the arm is manually controlled by the operator with a button to unlatch and latch the arm to allow movement. | 3 joint scissor arm with manual motion control. Locking mechanisms are used to manually loosen and lock the arm into place. | Similar. Comparison of technical equivalence below. |
| Performance Standards Tested | IEC60601-2-8<br>Standard for Radiation Therapy Devices | IEC60601-2-8<br>Standard for Radiation Therapy Devices | Equivalent – meets recognized requirements at time of manufacture |
| Electrical Safety Standards Tested | IEC60601-1 | IEC60601-1 | Equivalent – meets recognized requirements at time of manufacture |
| Red Diode Laser Pointing Capability | IEC Laser Class 3R Max output: 5mW Wavelength: 650 nM | Red-Diode Laser<br>U.S. Laser, Inc. (Item M650-5CH-V2)<br>FDA Laser Class: 3A; IEC Laser Class: 3R FDA Accession #: 95R2254<br>Wavelength: 650nM Max Power: 5mW Beam Divergence: 15 deg max | Equivalent |

The The GentleBeam is substantially equivalent to the predicate, the SRT-100 Vision System, due to the amount of similar key performance characteristics such as the indications for use, x-ray photons therapy modality, the emission of electrons using cathodes, and the spherical geometry of the emitted dose.

The dose rates between the two systems are similar. The GentleBeam has a maximum dose range of 500-1500 cGy/min, depending on the energy level, compared to the predicate, which has a dose range of 400-1000 cGy/min. The average treatment dose per fraction for treating non-melanoma skin cancer with superficial radiotherapy is approximately 250 cGy. This puts the treatment time for the GentleBeam at a range of 10-30 seconds, which is nearly equivalent to the predicate treatment time of 15-37 seconds.

The X-ray source current of 2-3mA on the GentleBeam is slightly different than the current of 8-10 mA on the predicate. This is based on the design of the source. The GentleBeam X-ray source has a transmission type target design which generates higher x-ray output with lower current as compared to the predicate device, which has a reflective target. The GentleBeam requires less current to reach the near equivalent dose rates.

The X-ray source filters are slightly different thickness on the GentleBeam when compared to the predicate. This thickness is to achieve equivalent beam quality on the GentleBeam to the predicate.

Focal spot size is slightly different due to the design of the transmission target of the x-ray source on the GentleBeam vs the reflective target of the predicate device. This allows for better symmetry and flatness of the GentleBeam when compared to the predicate device.

The secondary difference between the GentleBeam vs the predicate is the ultrasound technology employed. The GentleBeam System uses a Laser Induced Ultrasound (LIUS) which is essentially ultrasound imaging, but instead of generating ultrasound waves with piezoelectric materials, it leverages the photoacoustic effect, i.e., the generation of ultrasonic waves via thermo-elastic conversion of light pulses in an optically absorbing medium which is in a dedicated layer deposited on a Fabry-Perot Interferometer (FPI) sensor.

Acoustic reconstruction uses a k-space method algorithm. Sound speed is defined through an autofocus algorithm maximizing image gradients. Imaging System LIUS approach is intrinsically volumetric and directly provides 3D image information.

In the Imaging System (LIUS) a thin black film is deposited on the FPI sensor to generate plane waves. Additionally, the overall sensor is covered with an expoxy coating both for mechanical protection and to block any light leakage from the FPI sensor making the modality safe for the operator without any protective eyewear. The laser beam is inside the device and is not accessible during operation.

A comparison between phantom images acquired with the Imaging System LIUS and the Cortex DermaScan C Ultrasound System from the predicate device can be found in attachment CH03.08.00 LIUS Validation Test.

The third difference is the mounting method of the x-ray source itself. The GentleBeam uses a manually operated robotic arm to hold and position the weight of the x-ray source in a stable manner. The arm is manipulated by the operator using buttons to unlatch the arm and allow free motion to place the x-ray source into position to deliver therapy. The workflow is the same as the predicate, which uses a 3-joint manually operated scissor arm to maneuver the x-ray source into place. The predicate has several manually operated latching mechanisms that must be tightened and loosened before each movement, while the robotic arm allows for unlatching and latching with a single button press.

**Conclusion Statement**

All the GentleBeam's intended use can be found in the intended use of the predicate device. Any technological changes to the device are minor, primarily as it pertains to industrial design, and do not raise new questions of safety or effectiveness.

All cited nonclinical tests performed by accredited laboratories (TUV Rheinland; Acertera) and per recognized standards (IEC 60601 series, IEC 62304, IEC 62366/60601-1-6) and AAPM TG-61 met acceptance criteria. Internal physics, imaging, verification, and validation studies corroborate that the subject device achieves its essential performance and is substantially equivalent to the predicate in safety and effectiveness. Full reports, Declarations of Conformity, and the verification/validation traceability matrix are included in the submission.

The primary difference between the GentleBeam and its predicate is the use of the robotic manipulator arm to control and provide a stable delivery of the radiation therapy, and the design of the LIUS system. Performance testing, along with verification and validation activities demonstrate that GentleBeam output for generating x-rays, producing images of the patient lesion, and holding the x-ray source in place to deliver treatment to the patient is as safe and effective, and performs as well as the predicate device. Therefore, GentleBeam can be considered substantially equivalent to the predicate device.