Varian Medical Systems, Inc.
% Peter Coronado
Sr. Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

October 6, 2023

Re: K231863
Trade/Device Name: ProBeam 360 Proton Therapy System v2.0 (Multiroom)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN
Dated: September 6, 2023
Received: September 6, 2023

Dear Peter Coronado:

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.

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.

Submission Number *(if known)*

K231863

Device Name

ProBeam 360° Proton Therapy System v2.0 (Multiroom)

Indications for Use *(Describe)*

ProBeam 360° Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

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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Premarket Notification - 510(k) Summary

ProBeam 360° Proton Therapy System version 2.0

I. Submitter's Name

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Dr. Lynn Allman, Senior Director Regulatory Affairs
Phone: 650-424-5369
E-mail: submissions.support@varian.com
Date Prepared: June 23, 2023

II. Device Information

Proprietary Name: ProBeam 360° Proton Therapy System version 2.0 (Multiroom)
Common/ Usual Name: Proton Therapy System
Classification Name: System, Radiation Therapy, Charged-Particle, Medical
Regulation Number: §892.5050
Product Code: LHN

III. Predicate Device

ProBeam 360° Proton Therapy System v1.0 (K221791)

IV. Reference Device

ProBeam Proton Therapy System v2.0 (K133191)

V. Device Description

The ProBeam 360° Proton Therapy System v2.0 (Multiroom) is designed to deliver radiation treatment in accordance with the physician's prescribed treatment plan.

Proton radiation therapy takes advantage of the Bragg peak characteristic of proton attenuation to minimize radiation of normal tissue outside the target volume. Varian markets two lines of proton therapy systems, the standard ProBeam Proton Therapy Systems and the smaller, newer ProBeam 360° Systems. The ProBeam 360° Proton Therapy System line of proton systems includes single-room (cleared in K221791) and multi-room configurations.

The ProBeam 360° System Multiroom (subject device) introduces the multi-room, compact configuration and includes the following primary components:

- Cyclotron (226MeV)
- Beam Transport System (energy selection system and beam transport system)
- Two (2) to five (5) Treatment Rooms: Rotating Isocentric Gantry room with attached scanning nozzle; and a treatment table
- One Treatment Control Room for each treatment room within the chosen configuration

VI. Indications for Use

ProBeam 360° Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

The indications for use and intended use of the subject device is the same as the predicate device.

VII. Comparison of Technological Characteristics with the Predicate Device

The ProBeam 360° System version 2.0 (Multiroom) introduces the multi-room configuration to the ProBeam 360° line of proton therapy systems. The ProBeam 360° System Multiroom is substantially the same as the predicate device, the ProBeam 360° Proton Therapy System v1.0 (ProBeam 360° System v1.0) as cleared in K221791. The systems share the same intended use, compact design, and equivalent technological characteristics. The significant difference between ProBeam 360° System v2.0 and ProBeam 360° System v1.0 is in the configuration of the device.

ProBeam 360° System version 2.0 (Multiroom) adds a multi-room, modular design wherein a customer site may choose to construct a system of two (2) to five (5) treatment rooms with a rotating gantry. The multi-room configuration allows users to deliver proton beam to a maximum of five (5) treatment rooms within one facility, as compared to a single-room system which would require multiple facilities to achieve the same treatment capacity. The multi-room technology has been derived from the reference device, the standard ProBeam Proton Therapy System v2.0 (ProBeam PTS v2.0) as cleared under K133191. The ProBeam 360° System Multiroom combines the compact design of the ProBeam 360° System v1.0 (K221791) with the modular, multi-room design of the ProBeam PTS v2.0 (K133191).

The multi-room configuration adds 14 new risks, modifies three (3) existing risks, triggers verification of two (2) existing risk control measures, and is implemented through three (3) primary design changes:

- Addition of Beam Ports
- Software change to facilitate beam request scheduling across multi room configuration
- Compact Gantry Room offered as multi-room system (from 2 to 5 treatment rooms)

In addition, the multi-room configuration introduces the following non-significant changes:

- New Scanning Nozzle System (SNS) High Voltage (HV) power supply due to obsolescence
- Fixed Defects inherited from the prior ProBeam release

Those primary changes affect four (4) device characteristics as identified in Tables 1 and 2.

- Beam Ports
- Treatment Room Configuration
- Software Release
- Beam Scheduler

Table 1. Comparison of Subject Device to ProBeam 360° System version 1.0 Predicate Device

Device Characteristic		Predicate Device: ProBeam 360° Proton Therapy System v1.0 K221791	Subject Device: ProBeam 360° Proton Therapy System v2.0	Comparison
Intended Use/ Indications for Use		ProBeam 360° Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	ProBeam 360° Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	Same
Radiation Source				
Accelerator		Isochronous Cyclotron	Isochronous Cyclotron	Same
Type of Coils		Superconducting Coils	Superconducting Coils	Same
Cooling Method		Helium Cryogen Cooling	Helium Cryogen Cooling	Same
Treatment Particle		Proton	Proton	Same
Cyclotron Energy		226 MeV	226 MeV	Same
Nominal Energy		69 MeV – 218 MeV	69 MeV – 218 MeV	Same
Beam Delivery				
Beam Transport System	Gantry Beam Line	Beam line with steerer, quadrupole, dipole and scanning magnets.	Beam line with steerer, quadrupole, dipole and scanning magnets.	Same
	Beam Ports	None	Beam Ports (assembly magnets, beam stop, and beam diagnostic)	Beam ports allow for beam assignment to selected treatment room(s) in a multi-room configuration. Refer to Table 3 for comparison to reference device.
Beam Angle Adjustment		Adjustable: Rotational type isocentric 360° Gantry	Adjustable: Rotational type isocentric 360° Gantry	Same
Beam Delivery		Beam Spot Scanning	Beam Spot Scanning	Same
Beam Spot Shape		Spot size expressed as 1σ (sigma) value of the gaussian profile of the beam in air at isocenter: σ = 3.8 mm ± 15% at 218 MeV σ = 4.4 mm ± 15% at 140 MeV σ = 5.9 mm ± 15% at 69 MeV	Spot size expressed as 1σ (sigma) value of the gaussian profile of the beam in air at isocenter: σ = 3.8 mm ± 15% at 218 MeV σ = 4.4 mm ± 15% at 140 MeV σ = 5.9 mm ± 15% at 69 MeV	Same
Beam Field Size		Max: 25cm (x) x 25cm (y)	Max: 25cm (x) x 25cm (y)	Same
Dose Rate		2 Gy/l/min	2 Gy/l/min	Same
Physical Characteristics				
Treatment Room Configuration		Single Gantry Room Compact configuration	Two (2) to five (5) gantry rooms	Modular, configurable system allows for multiple treatment rooms in one installation. Refer to Table 3 for comparison to reference device.
Patient Positioning		Leoni Orion 6-AxisRobotic Treatment Table (K160518)	Leoni Orion 6-AxisRobotic Treatment Table (K160518)	Same
Maximum Load		226 kg (500 lbs)	226 kg (500 lbs)	Same
Imaging				

Table 1. Comparison of Subject Device to ProBeam 360° System version 1.0 Predicate Device

Device Characteristic	Predicate Device: ProBeam 360° Proton Therapy System v1.0 K221791	Subject Device: ProBeam 360° Proton Therapy System v2.0	Comparison
Patient Position Verification System	2D and image acquisition CBCT, nozzle mounted	2D and image acquisition CBCT, nozzle mounted	Same
Image Acquisition	Functionality included in PVA / Imaging Supervisor. 2D and CBCT (3D) image acquisition.	Functionality included in PVA / Imaging Supervisor. 2D and CBCT (3D) image acquisition.	Same
Software			
Version	ProBeam 360° version 1.0	ProBeam 360° version 2.0	Support multi-room configuration of the system including the Beam Scheduler. Refer to Table 3 for comparison to reference device.
Beam Priority	Beam priority can be assigned to the single treatment room	Beam priority is able to be assigned and prioritized in each treatment room prior to beam delivery.	Substantially equivalent to ProBeam 360º v1.0 (K221791)
Beam Scheduler	Beam request applies only to single room	Beam request must be scheduled among multi-room configuration (2 to 5 treatment rooms)	Allows for beam assignment to selected treatment room(s) in multi-room configuration. Refer to Table 3 for comparison to reference device.
Network Connectivity	Remote Monitoring and Limited Remote control	Remote Monitoring and Limited Remote control	Same
2D/3D Match	Integration of 2D/3D algorithm into P2VA	Integration of 2D/3D algorithm into P2VA	Same
CBCT Imaging	3D CBCT reconstruction algorithm	3D CBCT reconstruction algorithm	Same
3D/3D Match	3D/3D registration algorithm for patient setup	3D/3D registration algorithm for patient setup	Same

Table 2. Comparison of Subject Device to Reference Device Multi-Room Configuration

Device Characteristic	**Reference Device** ProBeam Proton Therapy System v2.0 K133191	**Subject Device** ProBeam 360° Proton Therapy System v2.0	**Comparison**
Intended Use / Indications for Use	ProBeam Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	ProBeam 360° Proton Therapy System v2.0 provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	Same as ProBeam PTS v2.0 (K133191)
Beam Delivery			
Beam Ports	60-degree Beam Ports (assembly magnets, beam stop, and beam diagnostic)	90-degree Beam Ports (assembly magnets, beam stop, and beam diagnostic)	Substantially the same as ProBeam PTS v2.0 (K133191). The 90-degree bend facilitates the smaller footprint of the ProBeam 360° v2.0.
Physical Characteristics			

Table 2. Comparison of Subject Device to Reference Device Multi-Room Configuration

Device Characteristic	Reference Device ProBeam Proton Therapy System v2.0 K133191	Subject Device ProBeam 360° Proton Therapy System v2.0	Comparison
Treatment Room Configuration	Two (2) to five (5) rotational type isocentric gantry rooms; or fixed beam rooms	Two (2) to five (5) rotational type isocentric gantry rooms	Substantially the same as ProBeam PTS v2.0 (K133191) for the gantry room. Gantry rooms in the ProBeam 360° System have a smaller footprint.
Software			
Beam Scheduler	Beam request must be scheduled among multi-room configuration (2 to 5 treatment rooms)	Beam request must be scheduled among multi-room configuration (2 to 5 treatment rooms)	Same as ProBeam PTS v2.0 (K133191)

VIII. Summary of Performance Testing (Non-Clinical Testing)

The ProBeam 360° System version 2.0 (Multiroom) and its corresponding software version have undergone formal design verification and design validation testing. Design verification and design validation testing demonstrates that the ProBeam 360° System Multiroom performs as intended and meets its essential performance. The software for the subject device is considered to have a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Hardware and software design verification and design validation testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, ISO 14971 Risk Management Standard, and IEC 62304 Software Life Cycle Process standard. Test results demonstrate conformance to applicable requirements specifications and assure hazard safeguards function properly.

Software design verification and design validation testing was conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 2005). Electrical Safety and Electromagnetic Compatibility (EMC) testing was performed for the ProBeam 360° System Multiroom. The system conforms to FDA recognized consensus standards for electrical safety and electromagnetic compatibility.

No animal studies or clinical tests have been included in this submission.

IX. Determination of Substantial Equivalence to the Predicate Device

A subset of technological characteristics and features of the subject device differs from the predicate device. These differences are all considered to be enhancements of the predicate, which facilitate the compact, multi-room design of the subject device, ProBeam 360° System Multiroom.

The intended use and indications for use are the same as the predicate device. Further, there are no changes in the principle of operation of the devices. The Verification and Validation demonstrates that the device is as safe and effective as the predicate. Varian therefore believes the data demonstrates that the ProBeam 360° System v2.0 is substantially equivalent to the predicate device, ProBeam 360° System v1.0 (K221791).