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

December 1, 2022

Re: K221791
Trade/Device Name: ProBeam 360º Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: LHN
Dated: October 28, 2022
Received: October 31, 2022

Dear Mr. 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 -S

Digitally signed by Lora D. Weidner -S
Date: 2022.12.01 19:38:07 -05'00'

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)*
K221791

Device Name
ProBeam 360° Proton Therapy System

Indications for Use *(Describe)*
The 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# Premarket Notification - 510(k) Summary

## ProBeam 360° Proton Therapy System version 1.0

K221791

**I. Submitter's Name**

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Mr. Peter J. Coronado, Senior Director Regulatory Affairs
Phone: 650-424-6320 | Fax: 650-646-9200
E-mail: submissions.support@varian.com
Date Prepared: 18 June 2022

**II. Device Information**

Proprietary Name: ProBeam 360° Proton Therapy System version 1.0
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 Proton Therapy System v2.0 (K133191)

**IV. Device Description**

The ProBeam 360° Proton Therapy System is a device that generates ionizing radiation (protons) in order to deliver radiation therapy in accordance with a predetermined treatment plan.

The ProBeam 360° System version 1.0 is available in single-room, compact configuration and includes the following primary components:

- Cyclotron
- Beam Transport System
- Treatment Room with a rotating Gantry
- Treatment Control Room

**V. 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.

**VI. Comparison of Technological Characteristics with the Predicate Device**

At a high-level, the subject device differs from the predicate device as a result of the following characteristics:

- Smaller Gantry
- Compact single Gantry room configuration
- Compact Beam Transport System

- Reduced-Energy Cyclotron
- Patient Positioning Robot
- CBCT acquisition
- Updated Software Release to support changes listed above

**Table 1. Comparison of Subject Device to Predicate Device**

| Device Characteristic | Predicate Device: ProBeam Proton Therapy System (K133191) | Subject Device: ProBeam 360° Proton Therapy System | 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 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 | 250 MeV | 226 MeV | Energy reduced cyclotron to allow compact Gantry design. Substantially equivalent to ProBeam K133191 |
| Nominal Energy | 70 MeV – 240 MeV | 69 MeV – 218 MeV | Reduced maximum beam energy to allow compact Gantry design. Substantially equivalent to ProBeam K133191 |
| **Beam Delivery** | | | |
| Beam Transport System | Standard beam optical system with quadrupoles and dipole magnets | Standard beam optical system with quadrupoles and dipole magnets | Same |
| Switching System | Yes | None | Single Room system does not require room switching capability as compared to multi-room system ProBeam K133191. |
| Beam Transport Magnets | Yes | Yes | Same |
| Beam Angle Adjustment | Adjustable: Rotating Isocentric Gantry rooms<br>Fixed: Fixed Beam Room | Adjustable: Rotating Isocentric Gantry room | Same as Adjustable in ProBeam K133191 |
| 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:<br>σ = 4.0 mm ± 15% at 240 MeV<br>σ = 4.0 mm ± 15% at 140 MeV<br>σ = 5.4 mm ± 15% at 70 MeV | Spot size expressed as 1σ (sigma) value of the gaussian profile of the beam in air at isocenter:<br>σ = 3.8 mm ± 15% at 218 MeV<br>σ = 4.4 mm ± 15% at 140 MeV<br>σ = 5.9 mm ± 15% at 69 MeV | Substantially the same beam characteristics as ProBeam K133191. |
| Beam Field Size | Max: 30cm (x) x 40cm (y) | Max: 25cm (x) x 25cm (y) | Reduced field size as compared to ProBeam K133191. |
| Dose Rate | 2 Gy/l/min | 2 Gy/l/min | Same |
| **Physical Characteristics** | | | |
| Treatment Room Configuration | Multi-Room | Single Gantry Room Compact configuration | Allows installation in building with small footprint. Single Gantry room is substantially equivalent to Rotating Isocentric |

**Table 1. Comparison of Subject Device to Predicate Device**

| Device Characteristic | Predicate Device: ProBeam Proton Therapy System (K133191) | Subject Device: ProBeam 360° Proton Therapy System | Comparison |
|---|---|---|---|
| | | | Gantry Rooms within ProBeam K133191. |
| Patient Positioning | Forte 6-AxisRobotic Treatment Table (K122413) | Leoni Orion 6-AxisRobotic Treatment Table (K160518) | Substantially equivalent |
| Maximum Load | 273 Kg (550lbs) | 226 kg (500 lbs) | New patient positioning system as cleared in K160518 supports up to 226 kg. |
| **Imaging** | | | |
| Patient Position Verification System | 2D image acquisition, wall-mounted or nozzle mounted | 2D image acquisition and CBCT, nozzle mounted | Adapted from reference device to allows for 3D image CBCT. Nozzle mounted same as predicate ProBeam K133191. |
| Image Acquisition | Functionality included in P2VA / Imaging Supervisor. Limited to 2D image acquisition. | Functionality included in PVA / Imaging Supervisor. 2D and CBCT (3D) image acquisition. | Allows for 3D image CBCT. See table 2 for comparison to reference device. |
| **Software** | | | |
| Version | Version 2.0 | ProBeam 360° version 1.0 | Supports changes for compact Gantry, patient positioning table, and operating system updates. |
| Network Connectivity | None | Remote Monitoring and Limited Remote control | Remote network connectivity enables the Varian service technicians to perform remote service activities. |
| 2D/3D Match | Integration of 2D/3D algorithm into P2VA | Integration of 2D/3D algorithm into P2VA | Same |
| CBCT Imaging | None | 3D CBCT reconstruction algorithm | Allows for 3D image CBCT. See table 2 for comparison to reference device. |
| 3D/3D Match | Not included | 3D/3D registration algorithm for patient setup | Allows for 3D image CBCT. See table 2 for comparison to reference device |

**Table 2. Comparison of Subject Device to Reference Device**

| Device Characteristic | Reference Device: TrueBeam System (K123291) | Subject Device: ProBeam 360 Proton Therapy System | Comparison |
|---|---|---|---|
| **Imaging** | | | |
| Patient Position Verification System | 3D CBCT | 3D CBCT | Same |
| Image Acquisition | Functionality included in PVA/ Imaging Supervisor | Functionality included in PVA/ Imaging Supervisor | 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 |

## VII. Summary of Performance Testing (Non-Clinical Testing)

Design verification and design validation testing demonstrates that the ProBeam 360° System v1.0 performs as intended and meets its essential performance defined as: the functionality enabling its intended use to deliver the radiation dose as prescribed for treatment.

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 showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly. Software design verification and design validation testing were conducted, and documentation was 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."

Electrical safety and electromagnetic compatibility (EMC) testing were performed for the ProBeam 360° System. 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 pre-market submission.

## VIII. 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, single-room design of the subject device, ProBeam 360° System.

The Intended Use and indications for use are substantially 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 v1.0 is substantially equivalent to the predicate device, ProBeam Proton Therapy System v.2.0 (K133191).