April 23, 2026

Varian Medical Systems, Inc.
Lynn Allman
Sr. Director, Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K252815
Trade/Device Name: ProBeam 360 Proton Therapy System v3.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN
Dated: September 3, 2025
Received: September 4, 2025

Dear Lynn Allman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252815 |

Please provide the device trade name(s).

ProBeam 360 Proton Therapy System v3.0

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

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

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# Premarket Notification - 510(k) Summary K252815

## ProBeam 360° Proton Therapy System version 3.0

### 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: September 3, 2025

### II. Device Information

Proprietary Name: ProBeam 360° Proton Therapy System version 3.0
Common/ Usual Name: Proton Therapy System
Classification Name: System, Radiation Therapy, Charged-Particle, Medical
Regulation Number: §892.5050
Product Code: LHN

### III. Predicate Devices

ProBeam 360° Proton Therapy System v1.0 (K221791) (single room configuration)
ProBeam 360° Proton Therapy System v2.0 (K231863) (multiroom configuration)

### IV. Device Description

The ProBeam 360° Proton Therapy System version 3.0 (ProBeam 360° System v3.0) is designed to deliver radiation treatment in accordance with the physician's prescribed treatment plan.

The ProBeam 360° Proton Therapy System v3.0 introduces several enhancements, including;

- Unified software for single and multiroom configurations
- Iterative Cone Beam CT (iCBCT) reconstruction algorithms
- and optional "HyperSight for ProBeam360" package (see below).

Minor changes include:

- Shared Framework Migration
- Secure DICOM
- Defect fixes inherited from the successor preceding ProBeam releases (PB6.0 and PB6.1MR1)

#### HyperSight for ProBeam 360°

HyperSight for ProBeam 360° is an advanced imaging package that builds upon Iterative Cone Beam CT (iCBCT) and extends the imaging capabilities of the ProBeam 360° System with additional features:

- Extended Field-of-View (FoV)
- Short-Arc CBCT
- Enhanced Imaging Performance

All HyperSight features are license-controlled and not available by default.

The addition of HyperSight for ProBeam 360° represents a significant advancement in volumetric imaging for proton therapy, supporting improved clinical workflow efficiency and precise target localization.

**Unified software for single room and multiroom configurations**

The ProBeam 360° System release version 3.0 (ProBeam 360° v3.0) includes software changes which enable clinical sites with installations of either ProBeam 360° System v1.0 (K221791) or ProBeam 360° system v2.0 (K231863) to upgrade to and run the same software version (version 3.0). There are no major changes to the hardware, and no changes to the site configurations in this release.

The ProBeam 360° System version 3.0 will be available as a software upgrade for both the single- and multi-room, compact configurations.

## 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.

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

## VI. Comparison of Technological Characteristics with the Predicate Devices

The ProBeam 360° Proton Therapy System v3.0 (ProBeam 360° System v3.0) introduces Iterative Cone Beam CT (iCBCT) to the ProBeam 360° line of proton therapy systems.

**Table 1. Comparison of Subject Device to ProBeam 360° System versions 1.0 and 2.0 Predicate Devices**

| Device Characteristic | | Predicate Device: ProBeam 360° Proton Therapy System v1.0 K221791 (Single room) | Predicate Device: ProBeam 360° Proton Therapy System v2.0 K231863 (Multiroom) | Subject Device: ProBeam 360° Proton Therapy System v3.0 | 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 | Standard beam optical system with quadrupoles, 50° and 140° dipoles and steering magnets. | Standard beam optical system with quadrupoles, 50° and 140° dipoles and steering magnets. Associated power supplies are connected to the magnets. Steerer power supplies directly, dipoles | Single-room (v1.0) installations: Standard beam optical system with quadrupoles, 50° and 140° dipoles and steering magnets.<br><br>Multi-room (v2.0) installations: Standard | Same |

**Table 1. Comparison of Subject Device to ProBeam 360° System versions 1.0 and 2.0 Predicate Devices**

| Device Characteristic | | Predicate Device: ProBeam 360° Proton Therapy System v1.0 K221791 (Single room) | Predicate Device: ProBeam 360° Proton Therapy System v2.0 K231863 (Multiroom) | Subject Device: ProBeam 360° Proton Therapy System v3.0 | Comparison |
|---|---|---|---|---|---|
| | | | and quadrupoles using switch gears. | beam optical system with quadrupoles, 50° and 140° dipoles and steering magnets. Associated power supplies are connected to the magnets. Steerer power supplies directly, dipoles and quadrupoles using switch gears | |
| | Beam Ports | Not included | Beam ports (assembly magnets, beam stop, beam diagnostic) Quadrupole, 30° dipole, and steering magnets. Associated power supplies are connected to magnets. Quadrupole and steerer directly and dipoles through switch gears. | Single-room (v1.0) installations: Not included<br><br>Multi-room (v2.0) installations: Beam ports (assembly magnets, beam stop, beam diagnostic) Quadrupole, 30° dipole, and steering magnets. Associated power supplies are connected to magnets. Quadrupole and steerer directly and dipoles through switch gears. | |
| 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:<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 | | 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 | 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 | Single gantry room compact configuration<br><br>Multiroom: two (2) to five (5) gantry rooms | Same |
| Patient Positioning | | Leoni Orion 6-AxisRobotic Treatment Table (K160518) | | Leoni Orion 6-AxisRobotic Treatment Table (K160518) | Same |

**Table 1. Comparison of Subject Device to ProBeam 360° System versions 1.0 and 2.0 Predicate Devices**

| Device Characteristic | Predicate Device: ProBeam 360° Proton Therapy System v1.0 K221791 (Single room) | Predicate Device: ProBeam 360° Proton Therapy System v2.0 K231863 (Multiroom) | Subject Device: ProBeam 360° Proton Therapy System v3.0 | Comparison |
|---|---|---|---|---|
| Maximum Load | 226 kg (500 lbs) | | 226 kg (500 lbs) | Same |
| **Imaging** | | | | |
| 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 |
| Iterative Cone Beam CT (iCBCT) image reconstruction | Not included | | iCBCT<br>iCBCT Acuros<br>iCBCT Acuros MAR | iCBCT – iterative image reconstruction algorithm<br>iCBCT Acuros – iCBCT image reconstruction algorithm with Acuros scatter correction<br><br>iCBCT MAR – iCBCT image reconstruction algorithm with Acuros scatter correction and metal artifact reduction |
| Extended Field of View | Not included | | Diameter of reconstructed CBCT 60-70cm | User can select the Field of View between Standard, Extended (60cm) and Maximum (70cm). |
| Short Arc CBCT | Not included | | Reduce the number of acquired projections; thus reducing the imaging time. New CBCT modes: ShortArc-Head, ShortArc-Spotlight | These modes allow a 150° scan arc, making the acquisition a few seconds faster. Reconstruction quality is a bit worse (artifacts are expected). |
| HU (Hounsfield Units) accuracy/uniformity | Not included | | Improved physics correction for scatter correction algorithms used on CBCT image reconstruction. | Ability to improve the HU values of images reconstructed with iCBCT Acuros and iCBCT Acuros MAR |
| Head125kV | Not included | | New CBCT mode "Head 125kV" introduced | Introduced acquisition mode that has the same parameters from the "Spotlight" mode, to align with the latest releases from our linacs. |
| **Software** | | | | |
| Version | ProBeam 360° version 1.0 | ProBeam 360° version 2.0 | ProBeam 360° version 3.0 | • Unified code base for ProBeam and |

**Table 1. Comparison of Subject Device to ProBeam 360° System versions 1.0 and 2.0 Predicate Devices**

| Device Characteristic | Predicate Device: ProBeam 360° Proton Therapy System v1.0 K221791 (Single room) | Predicate Device: ProBeam 360° Proton Therapy System v2.0 K231863 (Multiroom) | Subject Device: ProBeam 360° Proton Therapy System v3.0 | Comparison |
|---|---|---|---|---|
| | | | | ProBeam 360° Software<br>• Treatment plan database configuration loading (DSS, BMS, SNS, TCM)<br>• Code/Interface updates (PPS PUI, PPS PCS, BMS)<br>• MCS defect fixes<br>• Beam Centering UX improvements for service and commissioning (BTS IOC, ACS) |
| Beam Scheduler | Beam request applies only to single room | Beam request must be scheduled among multi-room configuration (2 to 5 treatment rooms) | While in single room systems the Beam request applies only to the single room, in multiroom systems the beam request must be scheduled among multiroom configuration (2 to 5 treatment rooms). | Samee |
| 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 |

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

The ProBeam 360° System version 3.0 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 v3.0 performs as intended and meets its essential performance. The following performance data was provided in support of the substantial equivalence determination.

**Product Verification and Validation Testing**

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.

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.

Performance testing of the ProBeam 360° System version 3.0 evaluated the new imaging features. Image quality performance testing was conducted to evaluate the Cone Beam CT (CBCT) and Iterative CBCT (iCBCT) imaging functionality of the ProBeam 360° System version 3.0, including iCBCT, iCBCT Acuros, iCBCT Acuros with Metal Artifact Reduction (MAR), Short-Arc CBCT, Extended Field-of-View CBCT, and new acquisition modes introduced in this release.

Image quality testing assessed parameters relevant to patient positioning and target localization, including spatial resolution, contrast resolution, uniformity, image noise, Hounsfield Unit (HU) accuracy and uniformity, geometric accuracy, and artifact behavior. Acceptance criteria were predefined based on internal design requirements, applicable IEC and AAPM imaging guidance, and performance benchmarks established by the predicate ProBeam 360° Systems.

Test results demonstrated that all evaluated CBCT and iCBCT imaging modes met their predefined acceptance criteria. Imaging performance was shown to be comparable to or improved relative to the predicate devices, and the enhancements did not introduce new risks related to image quality or patient positioning.

**Software Verification and Validation Testing**

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 Device Software Functions" (June 2023).

Comprehensive software testing was performed, including unit, integration, and system-level tests, as well as risk-based testing for safety-critical functions. Testing demonstrated that all software functions operated as intended within defined use conditions.

The software for the subject device is considered to have an 'enhanced' level of documentation, since a failure or flaw in the software could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

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

## VIII. Determination of Substantial Equivalence to the Predicate Devices

A subset of technological characteristics and features of the subject device differs from the predicate devices as introduced by the addition of iCBCT with optional "Hypersight for ProBeam360". These differences are all considered to be enhancements of the predicates, aimed at improving imaging quality and clinical performance characteristics of the ProBeam 360° System v3.0.

The intended use and indications for use are the same as the predicate devices. Further, there are no changes in the principle of operation of the devices. Verification and Validation supports that the device demonstrates substantial equivalence to the predicate devices. Varian therefore believes the data demonstrates that the ProBeam 360° System v3.0 is substantially equivalent to

the predicate devices, ProBeam 360° System v2.0 (K231863) and ProBeam 360° Proton Therapy System v1.0 (K221791).