July 8, 2026

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

Re: K260750
Trade/Device Name: Virtual Cone (1.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: March 6, 2026
Received: March 6, 2026

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.	K260750

Please provide the device trade name(s).

Virtual Cone (1.0)

Please provide your Indications for Use below.

The Virtual Cone plan insertion tool is an ESAPI script intended to facilitate the noninvasive treatment of small, spherical intracranial targets by automating part of the planning process within the Eclipse Treatment Planning System. It enables the generation, by clinical users, of precise, conformal dose distributions comparable to those achieved with physical stereotactic cones, streamlining the treatment planning and delivery process. To achieve this, the script automates the creation of a fixed, small MLC-defined aperture by generating a standardized control point sequence with sinusoidal dose rate modulation.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Premarket Notification - 510(k) Summary (K260750)

Traditional 510(k) Submission for Virtual Cone (1.0)

I. Submitter's Name

Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Lynn, Allman, PhD., Senior Director Regulatory Affairs
Phone: (650) 424-5369
E-mail: submissions.support@varian.com
Date Prepared: July 7th, 2026

II. Device Information

Proprietary Name: Virtual Cone (1.0)
Classification Name: Medical charged-particle radiation therapy system
Regulation Number: §892.5050
Product Code: MUJ

III. Predicate Device

Eclipse Treatment Planning System v18.1 (K242378)

IV. Device Description

Virtual Cone is software that is based on the technique described by Popple (Popple et al., 2018, see **References** section) and inserts candidate SRS photon treatment plans that allow for the treatment of small spherical, intracranial targets without the use of physical cones.

The Virtual Cone plan insertion tool enables the generation, by clinical users, of precise, conformal dose distributions comparable to those achieved with physical stereotactic cones, streamlining the treatment planning and delivery process. Virtual Cone qualifies as a medical device accessory because it is intended for use in the treatment of disease when used with the Eclipse Treatment Planning System. It is not intended to be used by itself but assists in the treatment planning process of the parent device (Eclipse Treatment Planning System).

Version 1.0 is limited to generation of Virtual Cone techniques with a dose distribution comparable to that delivered with a 5.0 mm physical stereotactic cone. It supports use with a 6X or 10X High Intensity mode beam (6FFF or 10FFF) on a TrueBeam or Edge accelerator equipped with a High Definition MLC. Virtual Cone is compatible with Eclipse Treatment Planning System v16.1, 18.0 and 18.1.

V. Indications for Use

The Virtual Cone plan insertion tool is an ESAPI script intended to facilitate the non-invasive treatment of small, spherical intracranial targets by automating part of the planning process within the Eclipse Treatment Planning System. It enables the generation, by clinical users, of precise, conformal dose distributions comparable to those achieved with physical stereotactic cones, streamlining the treatment planning and delivery process. To achieve this, the script automates the creation of a fixed, small MLC-defined aperture by generating a standardized control point sequence with sinusoidal dose rate modulation.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device and the predicate device have the same technological characteristics with respect to SRS cone planning workflow, with differences limited to the automation of existing manual planning steps within Eclipse TPS. These differences do not introduce new functionality and do not represent a change in the fundamental technology used for treatment planning.

The predicate device supports SRS physical cone planning through standard Eclipse functionality, in which the user manually performs the following steps:

- creation of a treatment plan,
- definition of cone size and beam geometry,
- manual configuration of arc geometry and delivery parameters,
- plan evaluation and approval within Eclipse.

The subject device (Virtual Cone) performs the same overall clinical task but introduces automation for specific workflow steps:

- the user defines a staging plan containing machine, energy, and isocenter parameters;
- the device automatically inserts arc geometry, MLC-defined apertures, and delivery parameters using predefined, validated templates;
- the resulting treatment plan is then evaluated, calculated, and approved using the standard Eclipse workflow.
    - *Note: these subsequent treatment planning steps within Eclipse are identical to the predicate device workflow*

Both the predicate device and the subject device are based on the same characteristics:

- Both the subject device and the predicate are radiotherapy treatment plan software applications. They are computer-based software devices used by trained medical professionals to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment.
- Both devices are used by the same type of clinical users.
- Virtual Cone is an accessory to the Eclipse Treatment Planning System and operates within the Eclipse environment using the Eclipse Scripting API.

Certain technological characteristics differ in that Virtual Cone 1.0 provides automation for the insertion of predefined stereotactic arc geometries and multileaf collimator apertures. These differences represent workflow automation of existing Eclipse TPS capabilities and do not change the fundamental principles of operation of the predicate device. All other planning functions performed by the clinical team, including dose prescription, dose calculation, plan review, and plan approval, remain exclusively within the standard Eclipse environment.

Comparison Table between Predicate Device and Subject Device

Feature/Specification	Predicate Device Eclipse TPS 18.1 (K242378)	Subject Device Virtual Cone 1.0	Comparison
General Details			
Intended Use Statement	The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments.	The Virtual Cone plan insertion tool is an ESAPI script intended to facilitate the non-invasive treatment of small, spherical intracranial targets by automating part of the planning process within the Eclipse Treatment Planning System. It enables the generation, by Clinical users, of precise, conformal dose distributions comparable to those achieved with physical stereotactic cones, streamlining the treatment planning and delivery process. To achieve this, the script automates the creation of a fixed, small MLC-defined aperture by generating a standardized control point sequence with sinusoidal dose rate modulation.	Virtual Cone 1.0 does not expand or modify the existing Eclipse TPS intended use/indications for use. It is an accessory to Eclipse TPS that automates part of the planning workflow already supported by Eclipse TPS.
Indications for Use			
Contraindications for Use	No contraindications for use	No contraindications for use	Identical
Environment	Professional healthcare facilities	Professional healthcare facilities	Identical
Type of Users	Qualified healthcare professionals	Qualified healthcare professionals	Identical
Cone Planning Workflow			
Type of Cone Planning	SRS physical cone planning	MLC-based SRS virtual (non-physical) cone planning	This pertains to the intended use of the subject device, Virtual Cone – that users are intended to plan radiation treatments that are comparable to those which include the use of physical cones. This occurs through the design and usage of virtual (as in software-based and algorithmically modeled) cones such that the physical cones are not utilized.

Feature/Specification	Predicate Device Eclipse TPS 18.1 (K242378)	Subject Device Virtual Cone 1.0	Comparison
Plan Setup	User manually creates an SRS treatment plan and selects physical cone configuration within Eclipse	User creates a photon staging plan with defined machine, energy, and isocenter as input to Virtual Cone	Substantially equivalent Both workflows begin with plan setup in Eclipse. Virtual Cone requires a staging plan but does not change intended use or planning scope.
Geometry Definition (Cone / Beam Geometry)	User manually defines cone size, arc geometry, couch/collimator angles, and beam parameters	User selects a predefined Virtual Cone template that defines arc geometry and beam parameters	Substantially equivalent Predicate supports manual definition of all geometric parameters. Virtual Cone applies predefined validated templates representing the same parameters.
Arc Creation / Configuration	User manually creates and configures arcs (angles, sequencing)	Automatically inserts standardized arcs using validated templates derived from staging plan	Substantially equivalent Predicate supports arc creation; Virtual Cone automates this exact workflow step without introducing new delivery mechanisms.
Collimation Approach	Achieved using physical stereotactic cones (fixed hardware geometry)	Achieved using fixed MLC-based aperture and standardized control-point sequence	Substantially equivalent Both produce small-field SRS dose distributions. Virtual Cone uses MLC-based implementation instead of hardware, within existing Eclipse capabilities.
Automation / Workflow Execution	All steps performed manually via Eclipse UI	Plan generation automated, including MLC aperture, arcs, and dose-rate modulation	Substantially equivalent Virtual Cone automates user-executable actions without introducing new planning capabilities or altering underlying algorithms.
Scripting Capability / Control	ESAPI scripting is available, but not required for cone planning; users perform planning through UI	Virtual Cone is a fixed ESAPI-based tool; scripts are not user-modifiable	Substantially equivalent Predicate provides scripting infrastructure; Virtual Cone uses it in a controlled, deterministic manner with no user programmability.
User Interaction	User manually defines all geometry and parameters	User selects staging plan and template; no direct parameter editing or scripting	Substantially equivalent Virtual Cone reduces manual input but does not introduce new user-controlled parameters.
MLC / Beam Parameter Configuration	Determined by cone hardware and user-defined beam settings	Programmatically applied from template and commissioning constraints	Substantially equivalent Parameters correspond to configurations achievable in Eclipse; Virtual Cone enforces validated machine/energy combinations.

Feature/Specification	Predicate Device Eclipse TPS 18.1 (K242378)	Subject Device Virtual Cone 1.0	Comparison
Dose Calculation	Performed using Eclipse algorithms (e.g., AAA/AXB)	Performed using same Eclipse algorithms after plan creation	Identical – Virtual Cone does not perform dose calculation.
Plan Review and Approval	User reviews and approves plan within Eclipse workflow	Identical Eclipse workflow used for review, QA, and approval	Identical – No change to clinical decision-making or QA workflow.
Treatment Delivery Compatibility	Plans delivered via standard Eclipse-integrated systems (e.g., TrueBeam)	Generated plans are delivered using same clinical workflow and systems, **see below limitations on delivery system support.**	Substantially equivalent Virtual Cone does not control delivery and produces plans compatible with existing systems.
Scope of Functionality	Full treatment planning workflow (including dose calculation, optimization, approval)	Limited to arc insertion only; all other planning remains in Eclipse	Substantially equivalent Virtual Cone does not expand functionality; it automates a subset of the existing workflow only.
Compatibility			
SRS Planning application	Yes	Yes, automated insertion of arcs into plan for SRS planning using 6X-FFF and 10X-FFF photon beams	Substantially equivalent Virtual Cone supports SRS treatments only using 6X-FFF and 10X-FFF photon beams
Treatment Delivery Support	TrueBeam and other delivery machines	TrueBeam only	Substantially equivalent Both devices support treatment delivery units. Virtual Cone is limited to a specific delivery system already supported by Eclipse TPS.
MLC Support	HD120 multi-leaf collimator and other MLCs	HD120 multi-leaf collimator only	Substantially equivalent Both devices support MLCs. Virtual Cone is limited to a specific MLC already supported by Eclipse TPS.

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

The following performance data was provided in support of the substantial equivalence determination.

Software Verification and Validation Testing:

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. Testing also included interoperability validation of the device within the intended operating software environment alongside the Eclipse Treatment Planning software. Software verification and validation was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

Cybersecurity and Interoperability requirements were assessed per FDA guidance's "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions (Feb 2026)" "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices (Sept 2017)".

Workflow and Implementation Validation Testing:

Device testing was performed to validate the accurate implementation of the Virtual Cone MLC-based SRS technique within a representative clinical case scenario. Completed alongside the validation of the full end-to-end clinical workflow was dosimetric validation of plans generated by the Virtual Cone script. Using a cranial phantom designed for SRS validation, the following steps for the clinical workflow simulation were completed by testers: CT simulation, treatment planning, image guidance (CBCT), delivery, and film/scintillator verification. Following delivery, film gamma analysis was completed.

The measured absolute dose to isocenter agreed with the Eclipse TPS calculation within 3%, and the high-resolution film dosimetry showed >99% gamma pass rates with 5%/1mm evaluation criteria (dose/distance tolerance). The implemented pre-treatment QA process demonstrated high sensitivity, with deliberate MLC aperture changes of ± 0.1 mm clearly identified.

Human factors Validation Testing:

Usability formative testing was conducted with representative users, physicists and dosimetrists, to obtain feedback on the user interface. Participants also provided overall impressions on the device and its use with their clinical workflows. From this study, no significant safety-related concerns were identified. All identified usability issues were evaluated for impact on task-safety or existing risk controls; no residual safety issues from use error remain after validated design and labeling changes.

Test results demonstrate conformance to applicable requirements and specifications.
No animal studies or clinical tests have been included in this pre-market submission.

Use of Consensus Standards:

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and efficacy.

ISO 14971:2019	Medical devices - Application of risk management to medical devices

IEC 62304:2006 + A1:2016	Medical Device Software - Software Lifecycle processes
IEC 62366-1:2015+A1:2020	Application of Usability Engineering to Medical Devices
IEC 82304-1:2016	Health software Part 1: General requirements for product safety
IEC 62083:2009	Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems
UL ANSI 2900-1:2017	Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
UL ANSI 2900-2-1:2017	Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
IEC 81001-5-1:2021	Health Software and Health IT Systems Safety, Effectiveness and Security - Part 5-1: Security - Activities In The Product Life Cycle

VIII. Determination of Substantial Equivalence to the Predicate

Virtual Cone is an accessory to the Eclipse Treatment Planning System and does not introduce a new intended use/indication. Virtual Cone automates a portion of an existing stereotactic radiosurgery planning workflow already supported by Eclipse TPS. These do not constitute a new intended use as Virtual Cone is used to support certain existing treatment planning workflows within the Eclipse TPS.

Certain technological characteristics differ in that Virtual Cone 1.0 provides automation for the insertion of predefined stereotactic arc geometries and multileaf collimator apertures. These differences represent workflow automation of existing Eclipse TPS capabilities and do not change the fundamental principles of operation of the predicate device.

Verification and validation demonstrate that the subject device is as safe and effective as the predicate. Varian therefore believes that the subject device is substantially equivalent to the predicate device.

IX. References

Popple RA, Wu X, Brezovich IA, Markert JM, Guthrie BL, Thomas EM, Bredel M, Fiveash JB. The virtual cone: A novel technique to generate spherical dose distributions using a multileaf collimator and standardized control-point sequence for small target radiation surgery. Med Phys. 2013;40(5):051707. doi:10.1118/1.4802752.