November 21, 2024

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

Re: K242874
Trade/Device Name: Gating Reflector Block
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 20, 2024
Received: September 23, 2024

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 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242874

Device Name
Gating Reflector Block

Indications for Use *(Describe)*
The Gating Reflector Block is an accessory medical device indicated for adult and pediatric patients undergoing radiotherapy treatment simulation and/or delivery. GRB is a reusable device indicated for monitoring patient motion including respiratory patterns.

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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K242874 Premarket Notification - 510(k) Summary

Gating Reflector Block

I. Submitter's Name

Varian Medical Systems
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: 20 September, 2024

II. Device Information

Proprietary Name: Gating Reflector Block
Regulation Number: §892.1750
Classification Name: Computed tomography x-ray system
Product Code: JAK
Common name: System, X-ray, Tomography, Computed

III. Predicate Device

Proprietary Name: Respiratory Gating for Scanners v2.0 (K213927)
(Gating Reflector Block is listed as a required accessory of RGSC v2.0)
Regulation Number: §892.1750
Classification Name: Computed tomography x-ray system
Product Code: JAK
Common name: System, X-ray, Tomography, Computed

IV. Device Description

The Gating Reflector Block is a passive hardware device used for tracking the respiratory motion of the patient. It is intended to be used as an accessory to with Respiratory Gating System Scanners (K213927); TrueBeam™, TrueBeam STx™, Edge™, VitalBeam (K213977); and RPM Respiratory Gating System 1.7MR2 (K102024) to support motion management during imaging acquisition or radiation therapy treatment.

The key performance characteristics of the device are as follows:

1. Consists of 4 radix lenses and can be tracked by infrared cameras.
2. Precise locating features for position and orientation
3. Passive hardware device
4. Non-sterile device
5. Suitable for patient contact on intact skin
6. It is reusable and cleanable.

The Gating Reflector Block (Figure 01) has the following major components:

1. Body
2. Reflective Markers

The device has 4 mounted optical markers such that the reflected light can be processed by a camera to quantify the displacement of the markers, thus obtaining the patient's breathing curve.
The device consists of a plastic block and back plate and the optical markers. The optical lenses reflect the IR light wavelengths used by parent devices. Their arrangement ensures that the spatial displacement and the rotation of the block is detectable by optical monitoring systems. The alignment to the treatment room lasers is ensured by the printed alignment marks on the top and the sides of the block.

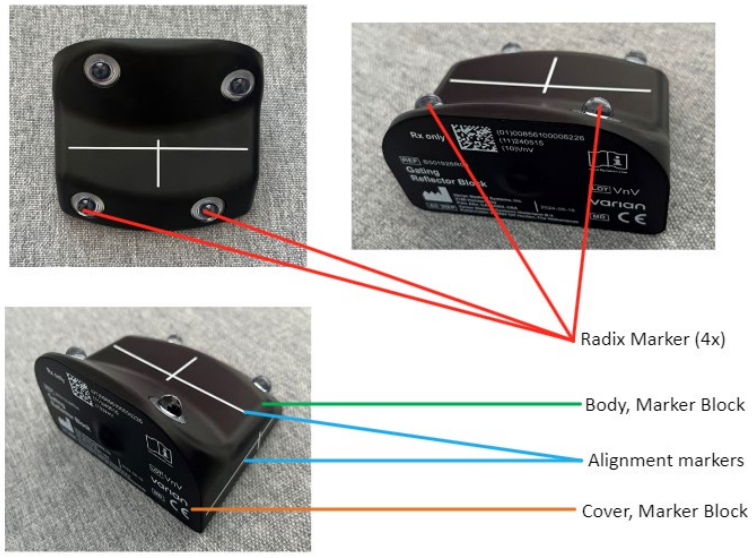

Figure 01: Gating Reflector Block

The major function of the device is to act as a surrogate device for tracking patient motion. Current parent devices track respiratory motion after placing the gating block on the chest of the patient. The IR reflectors are used by the parent devices to calculate the position and rotation of the block.

Note: With the parent devices, the subject device has been called by these names in addition to Gating Reflector Block: HET Marker Block, Reflector block, 4 dot block, Truebeam reflector block. This 510k aims to unify this into one name 'Gating Reflector Block'.

V. Intended Use

The Gating reflector block is intended to be used together with radiotherapy delivery systems or respiratory gating and motion management systems to track breathing pattern and / or other patient motions during a treatment or image acquisition.

VI. Indications for Use

The Gating Reflector Block is an accessory medical device indicated for adult and pediatric patients undergoing radiotherapy treatment simulation and/or delivery. GRB is a reusable device indicated for monitoring patient motion including respiratory patterns.

VII. Comparison of Technological Characteristics with the Predicate Device

Table 1 Comparison of Subject Device to Predicate Device

Features and/or specification	Predicate Device Respiratory Gating for Scanners 2.0 K213927 *(Gating Reflector Block is listed as a required accessory of RGSC v2.0)*	Subject Device Gating Reflector Block	Comparison
Device Name	Respiratory Gating for Scanners v2.0 Gating Reflector Block The Gating Reflector block is a required accessory of Respiratory Gating for Scanners v2.0 cleared under K213927	Gating Reflector Block	Changed. Gating Reflector Block was cleared as a required accessory for Respiratory Gating for Scanners v2.0 in K213927 and will now be registered as an individual product.
Intended use	Respiratory Gating for Scanners (RGSC) is used to characterize the patient's respiratory patterns, providing the necessary information to diagnostic devices to acquire images synchronized with the breathing motion. RGSC can also be used to monitor the patient position during the image acquisition. [The Gating Reflector Block is a required accessory of RGSC cleared under K213927] RPM Gating Marker Block and Gating Reflector Block are intended to be used together with radiotherapy delivery systems or respiratory gating and motion management systems to track breathing pattern and / or other patient motions during a treatment or image acquisition.	The Gating reflector block is intended to be used together with radiotherapy delivery systems or respiratory gating and motion management systems to track breathing pattern and / or other patient motions during a treatment or image acquisition.	Changed. Gating Reflector Block was cleared as a required accessory for Respiratory Gating for Scanners v2.0 in K213927 and will now be registered as an individual product. A separate intended use statement is now defined for Gating Reflector Block.

Features and/or specification	Predicate Device Respiratory Gating for Scanners 2.0 K213927 *(Gating Reflector Block is listed as a required accessory of RGSC v2.0)*	Subject Device Gating Reflector Block	Comparison
Indications for use	Respiratory Gating for Scanners (RGSC) is used to characterize the patient's respiratory patterns, providing the necessary information to diagnostic devices to acquire images synchronized with the breathing motion. RGSC can also be used to monitor the patient position during the image acquisition.	The Gating Reflector Block is an accessory medical device indicated for adult and pediatric patients undergoing radiotherapy treatment simulation and/or delivery. GRB is a reusable device indicated for monitoring patient motion including respiratory patterns.	Changed. Gating Reflector Block was cleared as a required accessory for Respiratory Gating for Scanners v2.0 in K213927. A separate indications for use statement is now defined for the Gating Reflector Block. To allow for use with all compatible delivery systems pediatric population has been specified with the gating reflector Block. While the Respiratory Gating for Scanners v2.0 does not include pediatric population in its indications for use, it has been adopted from its other parent device TrueBeam. The TrueBeam indications for use is inclusive of pediatric population.
Compatible Delivery Systems	Respiratory Gating Scanners (RGSC) [K213927] RPM Gating for Scanners 1.7MR1 [K102024] HET system [K213977]: • TrueBeam • TrueBeam STx • Vitalbeam • Edge	Respiratory Gating Scanners (RGSC) [K213927] RPM Gating for Scanners 1.7MR2 [K102024] HET system [K213977]: • TrueBeam • TrueBeam STx • Vitalbeam • Edge	Substantially the same.
Design	Light plastic block with passive reflective markers (4 dots)	Light plastic block with passive reflective markers (4 dots)	No change.
Dimensions	87.7mm x 77.5 mm x 53.4 mm	88mm x 77mm x 53 mm	Substantially the same.
Material	Acrylonitrile-Butadiene-Styrene Copolymer (ABS) 737	Acrylonitrile-Butadiene-Styrene Copolymer (ABS) 737	No change.

Features and/or specification	Predicate Device Respiratory Gating for Scanners 2.0 K213927 *(Gating Reflector Block is listed as a required accessory of RGSC v2.0)*	Subject Device Gating Reflector Block	Comparison
Positioning	Positioned typically on the patient's upper abdomen or chest area within the video camera's field of view during use.	Positioned typically on the patient's upper abdomen or chest area within the video camera's field of view during use.	No change.
Measured Parameters	Vertical, lateral, and longitudinal position of the gating reflector block. Alignment markers are located on the sides and top of the device to allow positioning and isocenter locations.	Vertical, lateral, and longitudinal position of the gating reflector block. Alignment markers are located on the sides and top of the device to allow positioning and isocenter locations.	No change.
Sterility	Provided nonsterile	Provided nonsterile	No change.
Packaging	Available in pack of 5	Available in pack of 5	No change.
Reprocessing, Sterility and Shelf life	Manual Cleaning	Manual Cleaning	No change in cleaning method. The Instructions for Use clarifies the Gating Reflector Blocks cleaning process.
Patient contacting components	The cover and the body are made up of ABS 737	The cover and the body are made up of ABS 737	No change.

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

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

Biocompatibility Testing

The biocompatibility evaluation for the subject device was conducted according to ISO 10993-1:2018: 'Biological Evaluation of a Medical Device – Part 1: Evaluation and Testing Within a Risk Management Process" and the FDA Guidance: "Use of International Standard ISO 10993-1, Biological evaluation and testing within a risk management process". The evaluation concluded that the Gating Reflector Block possess a low level of biological risk with an acceptable level of patient safety.

Cleaning, Disinfection, Sterilization, Reprocessing

Gating Reflector Block is supplied nonsterile. Cleaning validation for the subject device was conducted according to AAMI, ISO standards and FDA guidelines to assess the effectiveness of the provided cleaning procedure for the device.

Product verification and Validation testing

Gating Reflector Block has undergone formal design verification and validation testing including usability testing; and it demonstrates the device performs as intended.
Testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, and ISO 14971 Risk Management Standard.

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.

Table 2 List of Consensus Standards

Standard			
AAMI ANSI 62366-1	AAMI TIR12	ISO 10993-1	ISO 10993-10
ANSI AAMI ST98	ISO 11737-1	ISO 10993-5	ISO 10993-18
ISO 10993-23	ISO 17664-2		

IX. Summary of non-applicable Testing

Clinical Testing

No animal or clinical studies were conducted.

Magnetic Resonance Testing (MR)

No MR claims are being made; thus, the MR Safety status of the Gating Reflector Block has not been evaluated.

Electrical Safety and Electromagnetic Compatibility (EMC)

Gating Reflector Block is a passive hardware device which does not contain any electrical or mechanical components. Therefore, no EMC testing is required. No electrical safety and electromagnetic compatibility tests have been included in this submission in support of the substantial equivalence discussion.

Software Verification and Validation Testing

Gating Reflector Block is a passive hardware device which does not contain or consist of software/firmware. No software verification and validation testing have been included in this submission in support of the substantial equivalence determination.

X. Determination of Substantial Equivalence to the Predicate Device

Gating Reflector Block has been on the market for 13 years with approximately 27,000 devices in the field and is currently cleared as an accessory with Respiratory Gating System Scanners (K213927); TrueBeam™, TrueBeam STx™, Edge™, VitalBeam (K213977); and RPM Respiratory Gating System 1.7MR2 (K102024). These devices are manufactured by Varian Medical Systems and Varian has decided to separately clear the Gating Reflector Block as a Class II accessory to medical devices. Gating Reflector retains its compatibility with all three parent devices. There is no change to the principle operation of the device. A separate indications for use and intended use statements are now defined for the Gating Reflector Block. Varian believes these changes remain substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness. No technological changes are introduced because of the separate indications for use and intended use. The results of verification and validation as well as conformance to relevant safety standards demonstrate that the device meets the safety and performance criteria. Varian considers Gating Reflector Block to be as safe and effective as the predicate and to perform at least as well as the predicate Gating Reflector Block which was prior included as an accessory to Respiratory Gating for Scanners v2.0 within K213927.