June 4, 2026

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

Re: K253026
Trade/Device Name: Respiratory Gating for Scanners (2.1)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: May 5, 2026
Received: May 5, 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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.	K253026

Please provide the device trade name(s).

Respiratory Gating for Scanners (2.1)

Please provide your Indications for Use below.

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.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K253026 Premarket Notification - 510(k) Summary

RGSC 2.1

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: 19 September 2025

II. Device Information

Proprietary Name: Regulatory Gating for Scanners (2.1)
Regulation Number: 21 CFR §892.1750
Classification Name: Computed tomography x-ray system
Product Code: JAK
Common name: System, X-Ray, Tomography, Computed

III. Predicate Device

Proprietary Name: Regulatory Gating for Scanners (2.0) (K213927)
Regulation Number: 21 CFR §892.1750
Classification Name: Computed tomography x-ray system
Product Code: JAK
Common name: System, X-Ray, Tomography, Computed

IV. Device Description

Respiratory Gating for Scanners (RGSC) is used to characterize the patient's respiratory patterns and to provide this information to diagnostic scanners. The receiving devices synchronize their operation with the respiratory motion. The acquired images and the patient's respiratory patterns can also be used for radiotherapy treatment planning and as a reference for respiratory-synchronized treatment. RGSC is primarily used to:

- Acquire respiration cycle by optically detecting the motion of the four reflective markers attached to the marker block, which is positioned on the patient's chest or abdomen.
- Acquire prospectively gated images with a diagnostic CT or PET CT Scanner.
- Acquire respiration synchronized 4D Images with a diagnostic CT or PET CT Scanner.

The device provides information about the respiratory motion of a patient to 3rd party imaging systems. This includes:

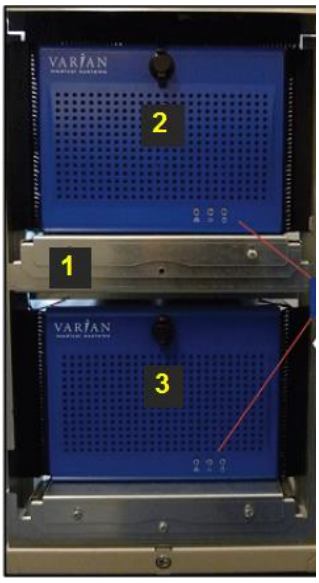
- Sending trigger signals to the scanner at specific amplitudes or phases of the patient's breathing cycle for a prospective 3D image acquisition.

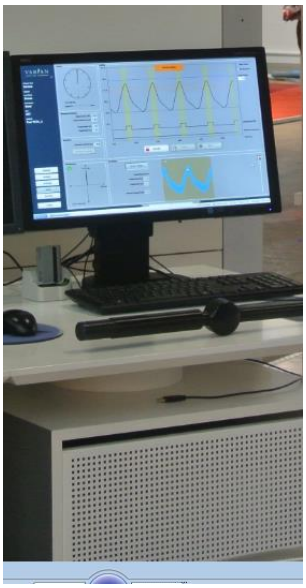
- Providing the scanner with breathing amplitude and phase information during the entire image acquisition for a retrospective 4D acquisition.

3rd party systems use that information to synchronize the image acquisition with the respiratory motion of the patient.

Figure 01 represents the RGSC system:

1. RGSC Cabinet
2. Workstation Unit
3. Real-Time Unit
4. Wireless Access Point – optional
5. Camera (on couch, wall, or ceiling)
6. Visual Coaching Device (Wireless) - optional accessory
7. Couch – separate medical device
8. Scanner – separate medical device
9. Gating Reflector Block – required accessory





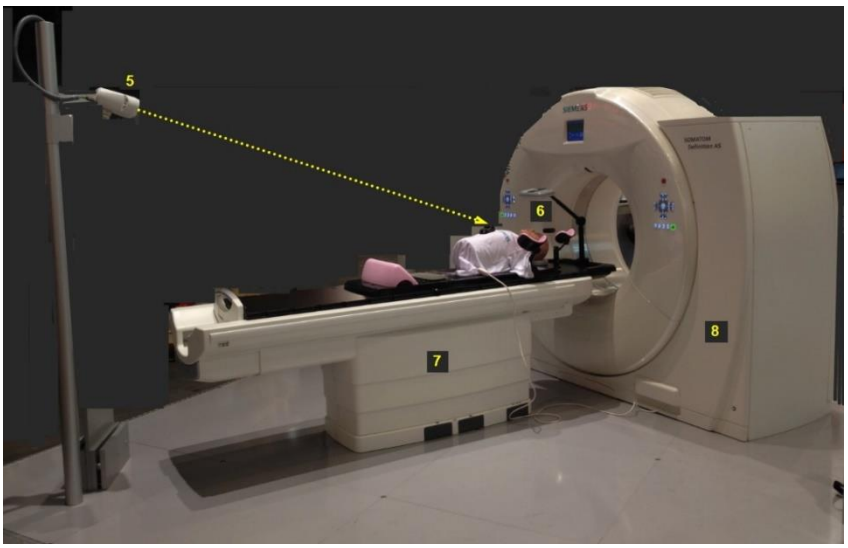


Figure 01: Respiratory Gating for Scanners (RGSC) being used in a Scanner Room

Note: The couch bending compensation feature is for specific compatible Siemens couches, and the feature is a model-based software correction designed to reduce respiratory baseline drift caused by mechanical deflection of supported Siemens patient couches, particularly under heavy loads. The models are derived from empirically measured table deflection data and reliant on user input of total patient and accessory load.

V. 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.

VI. 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.

VII. Comparison of Technological Characteristics with the Predicate Device

Table 1 Comparison of Subject Device to Predicate Device

Features and/or specification	Predicate Device RGSC 2.0 K213927	Subject Device RGSC 2.1	Comparison
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.	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.	Same
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.	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.	Same
General Usage:			
Non-linear couch deflection compensation	No	**Yes**	**Changed, substantially similar. This is the compensation of the baseline drift for specific Siemens couch types which is needed due to the deflection of the couch when the couch is extended to the CT-bore and especially when the load on the couch is large.**

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

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

Electrical Safety and Electromagnetic Compatibility (EMC)

RGSC has undergone EMC Testing. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Product verification and Validation testing

RGSC has undergone formal hardware and software verification and validation testing including usability testing; and it demonstrates the device performs as intended. Additionally, the sensitivity and accuracy testing were conducted to validate the compensated signal and assess model sensitivity to input weight.

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 and the other FDA recognized consensus standards listed in Table 2.

Software Verification and Validation Testing

RGSC has undergone software verification and validation testing and documentation has been provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

The documentation level required for RGSC 2.1 is "Enhanced", as a failure or flaw of the software function(s) could present a hazardous situation with probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use, as noted in the Level of Concern. The software for this device is considered as 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.

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			
ISO 14971:2019	ISO 15223-1:2021	IEC 80001-2-2: 2012	IEC 60601-1:2005/AMD2:2020
IEC 61217:2011	IEC 62366-1:2015 +A1:2020	IEC 80001-1:2021	IEC 60601-1-2:2014 +A1 2021
ISO 20417:2021	IEC 62304:2006+A1:2015	IEC 81001-5-1:2021	IEC 60601-1-6:2010/AMD2:2020
IEC 60825-1:2014			

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 RGSC has not been evaluated.

Biocompatibility Testing
There are no tissue contacting components in RGSC, therefore biocompatibility evaluation does not apply to this device.

Cleaning, Disinfection, Sterilization, Reprocessing
RGSC is supplied nonsterile.

X. Determination of Substantial Equivalence to the Predicate Device

The intended use and indications for use are the same as the predicate device. There is no change to the principle operation of the device. Varian believes the major technological characteristics are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness. 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 RGSC 2.1 to be as safe and effective as the predicate and to perform at least as well as the predicate device (K213927).