January 14, 2022

Varian Medical Systems, Inc.
% Peter Coronado
Senior Director, Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

Re: K213927
Trade/Device Name: Respiratory Gating for Scanners v2.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: December 15, 2021
Received: December 16, 2021

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213927

Device Name
Respiratory Gating for Scanners v2.0

Indications for Use *(Describe)*
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.

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.

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510(k) Summary (K213927)

The following information is provided as required by 21 CFR 807.92.

SUBMITTER	
Name and Address:	Varian Medical Systems, Inc. 3100 Hansen Way, m/s E110 Palo Alto, CA 94304
Contact Person:	Peter J. Coronado Senior Director, Regulatory Affairs Phone: 650-424-6320 | Fax: 650-646-9200 submissions.support@varian.com
Date Prepared:	January 11, 2022

SUBJECT DEVICE	
Subject Device Name:	Respiratory Gating for Scanners v2.0
Common/Usual Name:	Respiratory Gating for Scanners
Regulation:	21 CFR 892.1750
Classification Name:	Computed Tomography X-Ray System
Regulatory Class:	Class II
Product Code:	JAK

PREDICATE DEVICE	
Predicate Device Name:	Respiratory Gating for Scanners (K151533)
Reference Device(s):	No reference devices were used in this submission

DEVICE DESCRIPTION

Respiratory Gating for Scanners (RGSC) is a respiratory motion monitoring device used in the breathing-synchronized acquisition of images on CT and/or PET CT Scanners. It first received FDA clearance in 2015 (K151533). The device consists of the RGSC cabinet (containing workstation unit & real-time unit for user control and interaction), a gating reflector block placed on the patient, a camera system which is used to monitor the reflector block and report the patient's respiratory motion to the workstation, and a visual coaching device. RGSC is operated primarily by radiologist technicians and/or radiotherapists with current licensure and/or certification as required by regional authority, in accordance with the

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prescription of radiologist or a radiation oncologist and under the general supervision of chief technologists and/or medical physicists, as required by regional authority.

The concepts in the operation of the device include:

1. Breathing-synchronized image acquisition
2. Breathing motion tracking and recording
3. Tracking, recording, and triggering with prospective and retrospective gating for diagnostic imaging

The infrared camera tracks the position and motion of the reflector block, which is placed on the patient's chest or abdomen during this process. This light, plastic block with four reflective markers which face the direction of the camera is in transitory contact with the patient's skin for a limited amount of time (< 24 hours). Within the camera housing, an illuminator ring emits the infrared light which reflects off the markers on the reflector block back to the camera. The camera can be either wall-mounted, ceiling-mounted, or couch-mounted. It directly connected to the RGSC cabinet through the back panel. The housing also contains the Class II laser used to calibrate the camera. This calibration is to be performed after installation and any time the camera's position has changed.

The RGSC cabinet houses the workstation unit and real-time unit. The workstation contains the RGSC application which has functions for patient file creation and storage, calibration of the system, set up, recording, and review of a reference session. The real-time unit contains software for the real-time image data processing, which is used in the dynamic tracking of the reflector block. The real-time unit controls the interface to the Wireless Access Point, Camera, and 3rd party diagnostic imaging scanner.

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified device, referred to as the "subject device" throughout this summary, is the release version v2.0 (version 2.0) of the Respiratory Gating for Scanners. The predicate device is the release version v1.0 MR1 (version 1.0 Maintenance Release 1; K151533) of the Respiratory Gating for Scanners.

Significant Changes in the subject device compared with the predicate device are as follows:

1. SmartTrack algorithm change to improve detection and tracking of the Reflector Block

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The SmartTrack algorithm in the predicate device was not able to detect the Reflector Block in some situations due to x-ray scatter and sometimes the tracking of the Reflector Block failed because of pixel noise in the raw images. The SmartTrack of the predicate device used the top, bottom, left and right pixel above the threshold to calculate the size of the Reflector Block. This method may lead to an invalid result after the internal check. In the subject device, the calculation of the Reflector Block size is improved that such noisy and bright pixels randomly caused by x-ray scatter can be removed from the Reflector Block size calculation. This increases the robustness of detecting the Reflector Block position.

2. Use of a new filtering method for noise reduction on the breathing amplitude signal

   The subject device, RGSC v2.0, uses a new Kalman filtering method to reduce the noise on the amplitude signal, which is a more robust method against couch motions compared to the predicate device using a simple sliding averaging filter.

3. Support for couch-mounted camera (in addition to previous wall- and ceiling-mounted camera)

   The predicate device only supports wall or ceiling mounting of the camera. The subject device also allows mounting the RGSC single camera on the scanner couches.

The significant changes compared between the predicate device and subject device do not extend or add to the indicated use for the cleared predicate device. The SmartTrack algorithm improvement for better detection and the use of a new Kalman filtering method for noise reduction do not change the core mechanism from that of the predicate, but to improve the quality and performance of the device. The additional support of couch-mounted camera can be considered an improvement to existing capabilities in the predicate device. This feature does not add or extend the indicated usage of the predicate device. The non-clinical Verification and Validation testing demonstrates that these changes do not negatively impact the safety and effectiveness of the subject device and the subject device performs its intended use as designed through the product's functional, usability, and safety requirements.

Non-Significant Cumulative Changes in the subject device compared with the predicate device include:

- New service workspace to show the connection status to RGSC workstation and real-time node, and show live feed from the single camera
- Support of Windows 10 (changed from Windows 7 Ultimate)
- Real-time node: support a new version of VxWorks
- New single board computer for Real-time node
- Shared Framework Integration
- National languages support
- Wireless Access Point (WAP) configuration tool updated to a new version

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- Infrared Camera changes:
  - Implementation of High-Resolution sensor in camera
  - Extended distance from camera to scanner isocenter
  - Allow inverted mounting of the camera for ceiling mounting
- Visual Couching Device (VCD) changes:
  - Software operating system changed from Windows CE to Android
  - Support touch screen
  - Digital video output to support HDMI goggles
  - Additional 3rd party couch tops supported for VCD mounting
- Ability to hide personally identifiable information for improved HIPAA compliance
- Addition of new scanners to the configuration list
- Minor usability and cybersecurity improvements
- Bug fixes

Note: *These changes evaluated against FDA's Guidance Deciding when to submit a 510(k) for a change to an existing device (Oct 2017) and Deciding when to submit a 510(k) for a software change to an existing device (Oct 2017) and recommended for Documentation are considered Non-Significant Cumulative Changes in this submission.*

The subject device RGSC v2.0 is a modified device of the predicate device, RGSC v1.0MR1. A device comparison table is shown below, and the feature / specification changes that occur in this modification have been highlighted in blue.

Feature / Specification	**Predicate Device: RGSC v1.0 MR1 (K151533)**	**Modified / Subject Device: RGSC v2.0 (K213927)**
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.	
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.	
Major Components	• RGSC Cabinet (Workstation Unit & Real-Time Unit) • Infrared Camera • Reflector Block • Visual Coaching Device (wireless)	

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Feature / Specification	Predicate Device: RGSC v1.0 MR1 (K151533)	Modified / Subject Device: RGSC v2.0
General Usage		
National Languages Support	No, only support selected languages	Yes
Compatible with Image Acquisition Systems used in Radiation Oncology and Diagnostics	Yes, (General interface) supports for both triggered/gated and 4D image acquisition.	Yes, (General interface) supports for both triggered/gated and 4D image acquisition.
Support for audio and visual patient coaching methods	Yes, incorporates an optional Visual Coaching Device (VCD) that includes monitor attached on the Scanner Couch top.	Yes, incorporates an optional Visual Coaching Device (VCD) that includes monitor attached on the Scanner Couch top.
Supported breathing methods	Free-breathing, voluntary breath-hold	Free-breathing, voluntary breath-hold
Supported scanning modes	Prospective and retrospective scans	Prospective and retrospective scans
Patient position monitoring	Yes	Yes
Recognition and management of periodicity changes in respiratory pattern	Yes	Yes
Support for phase-based gating	Yes	Yes
Support for amplitude-based gating	Yes	Yes
Database Mode (connection to ARIA DB)	Yes	Yes
Export real-time data to 3rd party systems for post-processes and sort the 4D images	Yes	Yes
Export session data or sections of the reference data (user-definable start time for VXP export)	Yes	Yes
Infrared Camera Features		
Support for wall-mounted camera	Yes, supports a tracking distance from 2.5 to 5.6 meters. Video camera with 25 mm lens.	Yes, supports a tracking distance from 2.5 to 5.6 meters. Video camera with 25 mm lens.
Support for ceiling-mounted camera	Yes, supports a tracking distance from 2.5 to 5.6 meters. Video camera with 25 mm lens.	Yes, supports a tracking distance from 2.5 to 5.6 meters. Video camera with 25 mm lens.

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Feature / Specification	Predicate Device: RGSC v1.0 MR1 (K151533)	Modified / Subject Device: RGSC v2.0
Support for couch-mounted camera	No	Yes, supports a tracking distance of 1.0 to 2.5 meters. Video camera with 12 mm lens.
Extended distance from camera to scanner isocenter	No	Yes
Use of HighRes sensor in camera	No	Yes
Laser for camera calibration	Yes	Yes
SmartTrack	Use top, bottom, left and right pixel above the threshold to calculate the size of the Reflector Block	Improved calculation method that noisy and bright pixels randomly caused by x-ray scatter can be removed from the Reflector Block size calculation
Noise filter for Single Camera	Averaging Filter	Kalman Filter
Reflector Block Features / Specifications		
Material	ABS 737	ABS 737
Design	Light plastic block with reflective markers (4 dots)	Light plastic block with reflective markers (4 dots)
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.
Measured parameters	Vertical, lateral and longitudinal position of the reflector block.	Vertical, lateral and longitudinal position of the reflector block.
Visual Coaching Device Features		
Support for system navigation using an external USB mouse	Yes	No
Support for system navigation using the touch screen	No	Yes
Support for video output to an external monitor	Yes	Yes
Support for video output to a projector	Yes	Yes
Support for video output to VGA compatible video goggles	Yes	No
Support for digital video output to HDMI compatible video goggles	No	Yes
Software Operating System		

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Feature / Specification	Predicate Device: RGSC v1.0 MR1 (K151533)	Modified / Subject Device: RGSC v2.0
RGSC Workstation	Windows 7 Ultimate	Windows 10
Real-Time Node	V1	V2
Single Board Computer	ROBO 8112 CPU E1275v3	ROBO 8113 CPU E1275v6
Visual Coaching Device	Windows CE	Android
CT Scanner Interface		
Universal scanner interface	Yes	Yes
Trigger signal to scanner	Single-ended	Single-ended or differential
RGSC System		
RGSC workstation hard drive	HDD	SSD
Firewall model	Juniper SRX 100	Juniper SRX 300
Ethernet Switch	DELL 2816	Part of Juniper SRX 300

SUMMARY OF PERFORMANCE DATA

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

Non-clinical Verification and Validation Testing

Hardware and Software verification and validation testing was conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards listed below to ensure that the system is working as designed. Test results demonstrate that the device conforms to design specifications and meets the needs of the intended users, including assuring risk mitigations were implemented and functioned properly.

Software verification and validation testing were completed and documented 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." The software for this device was considered as a "major" level of concern (Class C per IEC 62304) as the device is an accessory to a medical device that has a "major" level of concern. The appropriate level software documentation is provided with reference to the relevant guidance.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were conducted on RGSC consisting of the electronic components: RGSC Cabinet (Workstation Unit and Real-time Unit), VCD, Wireless Access Point, and Infrared Camera.

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The system complies with the FDA recognized standards IEC 60601-1 for electrical safety and IEC 60601-1-2 for EMC.

Mechanical Testing

Mechanical testing and simulated use testing were conducted for camera couch mounting to ensure it works as designed and meets intended requirements specifications.

Human Factors Validation

Human factors validation study was conducted according to the standard IEC 62366 to verify the RGSC v2.0 performs well as intended for the intended users, uses, and use environments.

Standards Conformance

The subject device conforms to the following regulatory standards including FDA recognized standards and references additional standards as applicable.

- ANSI / AAMI ES60601-1:2005 + A1:2012 [FR 19-4]
- IEC 60601-1-2:2014 Edition 4.0 [FR 19-8]
- IEC 60601-1-6:2010+AMD1:2013 Edition 3.1 [FR 5-89]
- IEC 62366-1:2015 Edition 1.0 [FR 5-114]
- ISO 10993-1:2018 Fifth Edition [FR 2-258]

The subject device also complies with the following non-FDA recognized standard:

- IEC 60825-1:2014

The subject device was designed and developed, including verification and validation testing, within an established Quality System compliant to:

- 21 CFR §820 – Quality System Regulation
- ISO 13485:2016
- ISO 14971:2019 Third Edition [FR 5-125]
- ISO 15223-1:2016 Third Edition [FR 5-117]
- IEC 62304:2006/A1:2016 Edition 1.1 [FR 13-79]
- ANSI / UL 2900-1:2017 First Edition [FR 13-96]

Clinical Testing

No animal or clinical tests are being submitted to establish substantial equivalence with the predicate device.

CONCLUSION

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The **Respiratory Gating for Scanners v2.0** is substantially equivalent to the predicate device **Respiratory Gating for Scanners v1.0 MR1 (K151533)**. The intended use and indications for use are the same. 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 subject device **Respiratory Gating for Scanners v2.0** meets the safety and performance criteria and is substantially equivalent to the predicate device **Respiratory Gating for Scanners v1.0 MR1 (K151533).**