DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

August 13, 2015

Re: K151533
Trade/Device Name: Respiratory Gating For Scanners
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 5, 2015
Received: June 8, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151533

Device Name
Respiratory Gating for Scanners

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510k Summary

510k Submission for Respiratory Gating for Scanners

As required by 21 CFR 807.92; Reference: FDA's Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"

I. SUBMITTER

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E-110 Palo Alto CA 94304-1038
Contact Name:	Peter J. Coronado
Position:	Director, Regulatory Affairs
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Email:	submissions.support@varian.com
Date Prepared:	Friday, June 5, 2015

II. DEVICE

Name of Device:	Respiratory Gating for Scanners
Common/Usual Name:	System, X-Ray, Tomography, Computed
Classification Name:	Computed Tomography X-ray System (21CFR892.1750)
Regulatory Class:	Class II
Product Code:	JAK

III. PREDICATE DEVICE

Name of Predicate:	RPM Respiratory Gating System
510(k) Number:	K102024

IV. DEVICE DESCRIPTION

Respiratory Gating for Scanners (RGSC) consists of the RGSC Cabinet (Containing Workstation Unit & Real-Time Unit), Infrared Camera, Reflector Block, and Visual Coaching Device. RGSC is used in the breathing-synchronized acquisition of images on CT and/or PET CT Scanners. RGSC is an accessory to these systems. RGSC is operated primarily by radiologist technicians and/or radiotherapists, in accordance with the prescription of radiologist or a radiation oncologist and under the general supervision of a chief technologists and/or medical physicists.

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 has four reflective markers which face the direction of the camera. The reflector block is in transitory contact with the patient's skin for a limited amount of time (< 24 hours). The Instructions for Use provides instruction on how to properly clean the block for re-use between patients. This component is not intended for sterilization.

Within the camera housing, an illuminator ring emits the infrared light which reflects off of the markers on the reflector block back to the camera. The camera is mounted either on the wall or ceiling along the central axis of the couch at a maximum distance of 4.0 meters from the block. The camera is 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 the 3rd Party Diagnostic Imaging Scanner.

No biologics or drugs are in this device. The device is not intended for single use. No parts of the system are provided sterile or are intended for sterilization.

The associated accessories include:

- Keyboard and Mount for RGSC Workstation
- Monitor for RGSC Workstation
- VCD Couch Mounting Arm
- VCD Battery Packs, Charging Station, and External DC Power Supply
- Wireless Access Point

V. INDICATIONS FOR USE

Indications for Use Statement: 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 Indications for Use statement for RGSC is not identical to the predicate device; however, the differences do not extend or add to the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have within their intended use the same application in obtaining respiratory-synchronized images and monitoring patient position during image acquisition.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Respiratory tracking and gating is the technological principle for both the subject and predicate device. It is based on using an infrared camera to recognize and monitor the position of a plastic reflector block with reflective markers placed on the patient's chest or abdomen. The collected respiratory pattern can be gated to trigger image acquisition by a CT or PET CT scanner.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Reflector Block - Plastic Block with Reflective Markers
- Infrared Tracking Camera - Used to Monitor the Movement and Location of the Reflector Block
- Placement of the Block on the Abdomen or Chest of the Patient to Measure Respiratory Motion
- Support for Audio or Visual Coaching to guide patient in breathing patterns
- Support for Phase-Based or Amplitude-Based gating

The following technological differences exist between the subject and predicate devices:

- Use of a wireless Visual Coaching Device (VCD) with couch mounting
- Use of a camera with different resolution
- Use of a different Reflector Block design
- Support for Database Mode (connection to ARIA DB)
- Support for Wide Screen Monitor Displays
- Introduction of Baseline Drift Display and Correction
- Introduction of Additional Image and Data Export Functions
- The predicate device is compatible for use with radiation therapy treatment devices whereas the subject device is not compatible for use with those types of devices
- The predicate device is compatible for use with radiation therapy simulators whereas the subject device is not compatible for use with those types of devices

Further details about the differences between the predicate and subject device are included in the Substantial Equivalence Discussion of this submission.

VII. PERFORMANCE DATA

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

Non-Clinical Tests:

Biocompatibility Testing:

The biocompatibility evaluation for the Reflector Block component of RGSC was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA.

The Reflector Block component of RGSC is considered skin contacting for durations of less than 24 hours. The primary material of contact in this component, ABS 737, has no identified health or environmental effects, and no leachable material can be identified under the conditions specified for use of RGSC.

Electrical Safety and Electromagnetic Compatibility (EMC):
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. The system complies with the FDA Recognized Standards AAMI ANSI ES 60601-1 for Basic Safety of Medical Electrical Equipment and IEC 60601-1-2 for EMC.

Software Verification and Validation Testing:
Software verification and validation testing were conducted and documentation was 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 a "major" level of concern as the device is an accessory to a device with "major" level of concern. The appropriate level software documentation is provided with reference to the relevant guidance.

Mechanical Testing:

- Testing of the VCD Couch Mounting
- Testing of the Camera Wall/Ceiling Mounting
- Simulated Use Testing

Animal Study:
No animal studies have been included in this submission.

Clinical Tests:

No clinical tests have been included in this submission.

VIII. CONCLUSIONS

The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrate that Respiratory Gating for Scanners should perform as intended in the specified use conditions. The data demonstrates that RGSC is as safe and effective as and performs as well as or better than the predicate device, RPM Respiratory Gating System (K102024) for the same use in respiratory-synchronized image acquisition and patient position monitoring during image acquisition.