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

February 15, 2018

Re: K173636
Trade/Device Name: Velocity
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 22, 2017
Received: November 24, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173636

Device Name
Velocity

Indications for Use *(Describe)*

Velocity is a software package that provides the physicians a means for comparison of medical data including imaging data that is DICOM compliant. It allows the display, annotation, volume operation, volume rendering, registration, and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Velocity is not intended for mammography.

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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Premarket Notification [510(k)] Summary

Velocity 4.0

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: February 6, 2018
Proprietary Name:	Velocity
Classification Name:	Image Processing System, Radiology 21 CFR 892.2050, Class II Product Code: LLZ
Common/Usual Name:	Picture Archiving and Communication System (Medical Imaging Software)
Predicate Devices:	Primary predicate: Velocity AI – K081076 Secondary predicate: MIM Y90 Dosimetry - K172218
Device Description:	Velocity is a software application providing relevant tools for Radiotherapy professionals to use while creating treatment plans. The Velocity device is a Picture Archiving and Communication System (medical imaging software). Velocity provides medical image processing designed to facilitate the oncology or other clinical specialty work flow by allowing the comparison of medical imaging data from different modalities, points in time, and / or scanning protocols. The product provides users with the means to display, co-register and analyze medical images from multiple modalities including PET, SPECT, CT, RT Dose and MR; draw Regions of Interest (ROI), calculate and report relative differences in pixel intensities, Standardized Uptake Value (SUV) or other values within those regions; and import / export results to/from commercially available radiation treatment planning systems and PACS devices. Co-registration includes deformable registration technology that can be applied to DICOM data including diagnostic and planning image volumes, structures, dose, and automatic anatomical atlas-based segmentation tools. Velocity is used as a stand-alone application on recommended Off-The-Shelf (OTS) computers supplied by the company or by the end-user.
Intended Use Statement	Velocity is a software package that provides the physicians a means for comparison of medical data including imaging data that is DICOM compliant. It allows the display, annotation, volume operation, volume rendering, registration, and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Velocity is not intended for mammography.
Indications for Use Statement	Velocity is a software package that provides the physicians a means for comparison of medical data including imaging data that is DICOM compliant. It allows the display, annotation, volume operation, volume rendering, registration, and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Velocity is not intended for mammography.

Technological Characteristics:

VELOCITY 4.0 – DEVICE COMPARISON TABLE		
FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	**VELOCITYAIS V2.0** **K081076**	**VELOCITY 4.0**
Indications for Use/Intended Use	VelocityAIS (VelocityAI) is a stand-alone software product that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. VelocityAIS (VelocityAI) is not intended for mammography diagnosis.	Velocity is a software package that provides the physicians a means for comparison of medical data including imaging data that is DICOM compliant. It allows the display, annotation, volume operation, volume rendering, registration, and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Velocity is not intended for mammography diagnosis.
General Usage/ Performance Features		
Image Study Importation	Yes DICOM, PET/SPECT/CT/MRI Dose	Yes DICOM, PET/SPECT/CT/MRI Dose Query/Retrieve automation added in 4.0
Image Structure Import, Save & Export to Treatment Planning Systems	Yes	Yes
Volume rendering	Yes	Yes 4D Cine Volume support in 4.0.0
Advanced Visualization and Navigation Features	Yes	Yes multi-volume view support in 4.0

Volume Operations	No	Yes
Diagnostic Image registration	Yes	Yes
Image Fusion	Yes Anatomical and Functional Images	Yes Anatomical and Functional Images
ROI & Contouring	Yes	Yes
Manual Contouring Tools	Yes	Yes
Image Analysis	Yes	Yes
Plan Review of imported plans or created dose composites	No	Yes
Oncology workflow automation	No	Yes
Image/ROI Export to DICOM RT	Yes	Yes
Secure login and data storage	Yes	Yes
Operating System Platform	Microsoft Windows XP 32 bit only/Windows 7, Vista MAC OSX 10.6	Microsoft Windows 7 & 10 (64 bit only)/ Windows Server 2008R2 (Citrix), 2012R2, 2016 MAC OS 10.12 Sierra, macOS 10.13 High Sierra
Multimodality DICOM Import		
Import and display DICOM CT, MR, DS, PET, RTS, RTP	Yes	Yes
Advanced Visualization & Navigation		
General image viewer with view layout selection and toolbars	Yes	Yes
Volume Operations		
User scaling of image volumes	No	Yes
Biological Effective Dose (BED) Scaling	No	Yes
Y-90 Microsphere Dosimetry –	No	Yes

conversion of SPECT to DS		
Automated Image-based Registration		
Manual registration editing	Yes	Yes
Auto Rigid Registration	Yes	Yes
Deformable Registration	Yes	Yes
Inverse deformable registration	No	Yes
Structure Guided deformable	No	Yes
Segmentation (Manual Contouring Tools and Atlas Segmentation)		
Manual Contouring tools	Yes	Yes
Atlas Auto-Segmentation	Yes	Yes
Image analysis with volumetric graphs		
Histograms and Voxel Assessment graphs	Yes	Yes
DVH statistics display	Yes	Yes
Plan Review		
Storage and display of DICOM RT Plans	No	Yes
Lesion volume tracking by associating structure with name tag	No	Yes
Navigator Semi-Automated Workflows		
Semi-automatic workflows to assist with common clinical image registration & analysis tasks	No	Yes
Adaptive Navigators to assist in offline dose review: includes workflows to create adaptive CT based on CBCT registration, copy plan to adaptive CT, and compare dose.	No	Yes
Security		
Logging of database activity	No	Yes

MIM Y90 Dosimetry (K172218) was determined to be a predicate for the RapidSphere SPECT Microsphere Dosimetry feature. Both features:
- are intended for post-treatment absorbed dose calculation and evaluation
- are compatible with Y90 PET and SPECT image types
- and use the Local deposition model for dose calculation.

Performance Data:

Software Verification and Validation Testing
Software verification and validation was 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 as a "major" level of concern.

Clinical Tests No clinical tests have been included in this pre-market submission.

Conclusions
The non-clinical data support the safety of the device and the software verification and validation demonstrate that the Velocity device performs as intended. Varian therefore considers Velocity 4.0 to be safe and effective and to perform at least as well as the predicate device.