October 25, 2017

Volcano Corporation
Courtney Moore
Regulatory Affairs Specialist
3721 Valley Centre Drive, Suite 500
San Diego, California 92130

Re: K172455
Trade/Device Name: CORE M2 Vascular System Software v4.2
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, DSA
Dated: August 11, 2017
Received: August 14, 2017

Dear Courtney Moore:

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 (DICE) 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 (DICE) 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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K172455

Device Name
CORE M2 Vascular System Software v4.2

Indications for Use *(Describe)*
The CORE M2 Vascular System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

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

SPONSOR:

Volcano Corporation
3721 Valley Center Drive
San Diego, CA 92130

CONTACT/SUBMITTER:

Courtney Moore
Regulatory Affairs Specialist
Volcano Corporation
3721 Valley Center Drive
San Diego, CA 92130
Tel: (858) 764-1308
Fax: (858) 481-1027

DATE PREPARED:

August 11, 2017

DEVICE:

CORE M2 Vascular System Software v4.2

TRADE NAME:

CORE M2 Vascular System Software v4.2

COMMON NAME:

Ultrasonic Pulsed Echo Imaging System

CLASSIFICATION:

21 CFR Part 892.1560
IYO: Ultrasonic Pulsed Echo Imaging System
21 CFR Part 870.2900
DSA: Patient Transducer and Electrical Cable
Class II Device

PREDICATE DEVICE:

Volcano s5i/CORE and CORE Mobile Precision Guided Therapy Systems (K153369, primary)
CORE M2 Vascular System (K170385)

DEVICE DESCRIPTION:

The CORE M2 Vascular System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures. The system utilizes the acoustic impedance of vascular structures to provide cross sectional images from inside the vessel. The IVUS catheter uses a transducer near the distal tip to emit and receive high frequency sound waves. The system is then able to analyze the signal that is received by the transducer to differentiate between vessel structures to produce a 360º cross sectional grayscale image.

In addition to producing grayscale IVUS images, the CORE M2 System with Software v4.2 provides the ChromaFlo feature which can be used to identify blood flow. The ChromaFlo feature uses patented technology to provide a visual depiction of blood flow through the vessel. This is accomplished by overlaying a two-dimensional color mapping of relative blood flow velocity on to the grayscale ultrasound image.

The CORE M2 Vascular System consists of a cart mounted touchscreen PC Console, a patient interface module (PIM) for connecting the IVUS Imaging Catheter to the PC Console, and an optional Control Console as an alternative to the touchscreen for control of the CORE M2 System.

INDICATIONS FOR USE:

The CORE M2 Vascular System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

COMPARISON OF CHARACTERISTICS:

The CORE M2 Vascular system is a modification Volcano's currently marketed CORE Mobile Precision Guided Therapy System which is a multi-modality platform that provides both Intravascular Ultrasound (IVUS) Imaging and pressure measurement capabilities.

The initial release and clearance of the CORE M2 Vascular System with Software v4.1 only included support for a limited set of catheters and features from what is currently available on the predicate CORE Mobile System. The purpose of this Special 510(k) is to obtain clearance for a modification to the CORE M2 System software to incorporate additional currently marketed Volcano features from the CORE Mobile System onto the CORE M2 System.

Via this submission, Volcano proposes the following software changes:

- Compatibility for the Visions PV.018 Digital IVUS Catheter and Pioneer PLUS Catheter
- Addition of the ChromaFlo feature
- Addition of DICOM network archiving capabilities
- Language translations of the user interface for international markets
- Security improvements
- Fixes for some unresolved anomalies that were deferred from Software v4.1

PERFORMANCE DATA:

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

Design Verification

Verification of the image acquisition card was performed to ensure it continues to meet specifications to support the software changes. The results of this testing demonstrates the CORE M2 System image acquisition card meets the defined specifications.

Bench testing and analysis was performed to compare the acoustic output of the CORE M2 System to the predicate device. For the CORE M2 Software v4.2, the additional catheters (PV.018 and Pioneer PLUS) and features (ChromaFlo) were examined. The output for the CORE M2 System was found to be substantially equivalent.

Software Verification and Validation

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Unit, integration, and system level software testing was conducted on the CORE M2 v4.2 software, consisting of the application, firmware, and imaging library. The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the

patient or operator. The results of the software verification and validation demonstrate that the CORE M2 v4.2 software meets the defined software requirements.

Simulated Use / Usability Validation

Simulated Use/Usability Validation testing was conducted to ensure the CORE M2 System meets the user needs, satisfies the intended use, and demonstrates that users are able to use the device safely and effectively. Simulated Use/Usability Validation testing was conducted for the new features and changes to the CORE M2 Software for version 4.2. The results of this validation demonstrate that the CORE M2 System meets the user needs.

Image Validation

An Image Validation was also conducted to confirm that the images acquired and displayed by the CORE M2 System are clinically acceptable for end users. Image validation was conducted for the additional catheters (PV.018 and Pioneer PLUS) and features (ChromaFlo) for the CORE M2 Software v4.2. The results of the image validation demonstrate that the CORE M2 system provides images which are clinically acceptable.

Summary

The results of the performance data for the CORE M2 System with Software v4.2 demonstrate substantial equivalence to the predicate device.