



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

December 22, 2015

Volcano Corporation
Brian Park
Sr. Regulatory Affairs Specialist
3721 Valley Centre Drive
San Diego, CA 92130

Re: K153369

Trade/Device Name: Volcano s5/s5i/CORE and CORE Mobile Precision Guided Therapy Systems

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic Pulsed Echo Imaging System

Regulatory Class: Class II

Product Code: IYO, DSK, DSA

Dated: November 20, 2015

Received: November 23, 2015

Dear Brian Park:

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

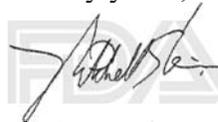
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153669

Device Name
Volcano s5/s5i/CORE and CORE Mobile Precision Guided Therapy Systems

Indications for Use (Describe)

The Volcano s5i®/CORE™ and CORE™ Mobile Precision Guided Therapy 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.

The VH® IVUS System is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

The iFR® Modality of the s5/s5i/CORE and CORE Mobile Precision Guided Therapy System is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. The iFR® Modality is intended to be used in conjunction with currently marketed Volcano pressure wires.

Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and the wall structures. The Pullback feature of the PIMr withdraws the imaging core within the protective sheath for a maximum of 15 cm.

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
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San Diego, CA 92130

CONTACT/SUBMITTER: Brian Park
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San Diego, CA 92130
Tel: (858) 720-4176
Fax: (858) 481-1027

DATE PREPARED: November 20, 2015

DEVICE: Volcano s5/s5i/CORE[®] and CORE[®] Mobile Precision Guided Therapy Systems

TRADE NAME: Volcano s5/s5i/CORE[®] and CORE[®] Mobile Precision Guided Therapy Systems

COMMON NAME: Ultrasonic Pulsed Echo Imaging System

CLASSIFICATION: 892.1560, Ultrasonic Pulsed Echo Imaging System, II, IYO
870.1110, Blood Pressure Computer, II, DSK
870.2900, Patient Transducer and Electrical Cable, II, DSA

PREDICATE DEVICE: CORE/CORE Mobile Precision Guided Therapy Systems (K133641)

s5/s5i Intravascular Ultrasound Imaging & Pressure Systems (K140291)

Volcano iFR Modality (K133323)

Volcano iFR Scout (K150441)

DEVICE DESCRIPTION: The Volcano s5i[®]/CORE[™] and CORE[™] Mobile Precision Guided Therapy System provides 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. Intravascular ultrasound (IVUS) 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 360° cross sectional image.

These grayscale images can then be enhanced using VH IVUS. VH analysis provides automatic border detection for the vessel and lumen borders, as well as plaque composition. Plaque is automatically classified into four categories in order to simplify interpretation of the IVUS image

Alternatively, the ChromaFlo feature can be used to identify the 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 onto the grayscale ultrasound image.

In the FFR (or pressure) mode, the system acquires intraluminal data from a pressure guide wire while simultaneously taking aortic pressure data from the established ECG/EKG catheterization laboratory equipment. The system will measure pressure from the transducer on the guide wire both proximal and distal to a lesion and will calculate the fractional flow reserve (FFR).

The iFR® Modality is similar to the FFR Modality in that both modalities are capable of taking pressure measurements and both modalities have the identical indications for use and use the identical pressure wires. The primary difference is a new software algorithm that evaluates a portion of the cardiac wave cycle. The FFR Modality is calculated based on the entire cardiac wave cycle, whereas the iFR® Modality is calculated by isolation of the cardiac wave cycle where intracoronary resistance is naturally constant and minimized and where intracoronary flow is maximized. This results in the ability to measure pressure without administration of a hyperemic agent with the iFR® Modality whereas the FFR Modality is calculated after administration of a hyperemic agent.

iFR® Pullback and Live iFR are new features added to the iFR® Modality that will allow the assessment of a lesion (spot measurement) or vessel (pullback measurement) in a resting condition without the requirement of a hyperemic agent. The iFR® Pullback feature will allow the user to assess a length of vessel by placing the pressure sensor distally, beginning recording/measuring, and pulling the sensor back through the vessel to a stopping point. This generates a “map” of the wave-free pressure gradient iFR® values along the vessel and a distal iFR® value that represents the condition of the vessel at the most distal point of the recording.

The rotational mode is available on the system with the Revolution catheter connected to the system via the PIMr (SpinVision). Cross-sectional images from inside the vessel are displayed on the monitor allowing the user to make measurements.

The CORE™ Control Pad is a touch screen accessory that is a secondary controller in the Volcano s5i®/CORE™ and CORE™ Mobile Precision Guided Therapy System (integrated and mobile systems). Images, data, and case navigation controls are relayed to and from the CORE™ Control Pad display via the system central processing unit (CPU). These images, data and controls are presented in a graphical user interface (GUI) displayed on the touch screen of the CORE™ Control Pad. The user may use the GUI to navigate IVUS and FFR cases and to make measurements on intravascular ultrasound images that are presented on the primary system display.

INDICATIONS FOR USE:

The Volcano s5i®/CORE™ and CORE™ Mobile Precision Guided Therapy 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.

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COMPARISON OF CHARACTERISTICS:

Via this submission, Volcano proposes the following software changes:

- Update the operating system of the Systems and CCP from Windows XP to Windows 7
- Update the software of the currently cleared CCP accessory to allow the user to use the CCP to switch the System easily between the FFR and iFR Modalities and activate iFR Scout on Systems that contain iFR and iFR Scout software

PERFORMANCE DATA:

Performance testing completed for a determination of substantial equivalence included the following:

- Software Verification
- Simulated Use / Usability Validation

The results of the performance data demonstrate equivalence to the predicate devices.