April 11, 2018

Volcano Corporation
Christopher McLellan
Manager, Regulatory Affairs
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K173860
Trade/Device Name: s5/s5i/CORE/CORE Mobile Precision Guided Therapy System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO
Dated: March 9, 2018
Received: March 12, 2018

Dear Christopher McLellan:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173860

Device Name

Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System

Indications for Use *(Describe)*

The Volcano 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.

VH IVUS 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.

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.

The FFR v2.5 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. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89 which represents an ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used as for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.

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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Section 2 – 510(k) Summary

I. Submitter

Volcano Corporation

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San Diego, CA 92130

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Date Prepared: December 19, 2017

II. Device

Name of Device:	Volcano s5™ /s5i/CORE/CORE™ Mobile Precision Guided Therapy System
Common or Usual Name:	Ultrasonic pulsed echo imaging system.
Classification Name:	System, Imaging, Pulsed Echo, Ultrasonic (21 CFR 892.1560).
Regulatory Class:	II
Product Code:	IYO

III. Predicate Device

Volcano s5™/s5i/CORE/CORE™ Mobile Precision Guided Therapy System (K133323).

Secondary Predicate Device

FFR v2.5 (K170133)

Reference Submissions for the Volcano s5™/s5i/CORE/CORE™ Mobile Precision Guided Therapy System:

- K133641
- K140291
- K150441
- K153369

IV. Device Description

The Volcano s5 TM/s5i/CORE/CORETM Mobile Precision Guided Therapy System is a mobile imaging and pressure management system as previously described in K133323. The subject device incorporates the Volcano iFR® Modality cleared in K133323.

Pressure measurement is captured through the use of currently marketed pressure wires compatible with the currently marketed s5/s5i/CORE/CORE Mobile imaging and pressure measurement system.

V. Indications for Use

The Volcano s5™/s5i/CORE/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.

VH IVUS 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.

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.

The FFR v2.5 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. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89 which represents an ischemic threshold and can reliably guide revascularization decisions during diagnostic

catheterization procedure. When used for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.

VI. Comparison with the Predicate Device

The predicate device is the currently marketed Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System iFR Modality (cleared under K133323 with the same trade name). This submission is for a change in the indications for use of the currently marketed device. The indications for use for the iFR Modality of the subject device has been revised to reflect the currently recognized, and clinically supported physiological, dichotomous 0.89 intravascular pressure index from a hybrid approach of 0.75 – 0.80 to provide information to help inform decisions on whether to perform or defer percutaneous coronary intervention (PCI). In the coronary anatomy, the iFR Modality has a diagnostic cut-point of 0.89 which represents an ischemic threshold and can reliably guide revascularization during diagnostic catheterization procedure. When used for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.

The Volcano FFR and iFR Modality Operator's Manual is being revised to include a dichotomous cut-point for Instantaneous Wave-free Ratio (iFR) guidance in coronary revascularization decision-making to replace the hybrid approach described in the Volcano FFR and iFR Modality Operator's Manual of the currently marketed device. There are no changes to the device materials or intended use.

The Volcano s5/s5i/CORE/CORE Mobile Intravascular Imaging and Pressure System and the predicate device share the **same intended use**. These devices are software developed and designed to measure blood pressure in the coronary and peripheral vasculature.

The Volcano s5™/s5i/CORE/CORE™ Mobile Precision Guided Therapy System and the predicate device share the **same general operating principal**. Both devices use the same pressure wires and are both compatible with only the Volcano imaging and pressure systems.

Volcano s5™/s5i/CORE/CORE™ Mobile Precision Guided Therapy System and the predicate device share the **same technological features**.

The only difference between the Volcano s5/s5i/CORE/CORE Mobile Intravascular Imaging and Pressure System with iFR® Modality and the predicate device is the **indications for use**. The indications for use for the iFR Modality of the subject device has been changed to measure intravascular blood pressure using the iFR Modality diagnostic cut-point of 0.89 which represents an ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.

The similarities between the subject Volcano s5/s5i/CORE/CORE Mobile Intravascular Imaging and Pressure System and the predicate device are illustrated in the table below.

Attribute/Feature	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System iFR Modality – K133323 (Predicate Device)	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System (Subject Device)
Indications for Use	The iFR Modality of the s5™/s5i/CORE/CORE™ Mobile Series 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.	The Volcano s5™/s5i/CORE/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. VH IVUS 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

Attribute/Feature	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System iFR Modality – K133323 (Predicate Device)	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System (Subject Device)
		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. 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. The FFR v2.5 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.

Attribute/Feature	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System iFR Modality – K133323 (Predicate Device)	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System (Subject Device)
		The iFR Modality is intended to be used in conjunction with currently marketed Volcano pressure wires. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89, which represents an ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.
Pressure Wires	SmartWire II, PrimeWire, PrimeWire Prestige, PrimeWire Prestige Plus, Verrata, Verrata PLUS	SAME
Patient Isolation	Contained in the Patient Interface Module (PIM): Electronic and Electrical Defibrillation proof Isolation through 8mm bare fiberglass PCA creepage with optical isolators and specially wound transformers with 5KV insulation.	SAME
Environmental Operating Temperature, Humidity and Pressure Range	• Operating Temperature: +10°C to +35°C • Operating / Storage Humidity: 10% ≤ RH ≤ 95% Non-condensing • Operating Pressure Range: 70-106kPa (526.3 – 797 mmHG) • Storage Pressure Range: 50-106kPa (376 – 797 mmHg)	SAME
Display	Control room	SAME

Attribute/Feature	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System iFR Modality – K133323 (Predicate Device)	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System (Subject Device)
	• 19" Non-medical grade powered through an isolation transformer Exam room • Use an existing Monitor in "Monitor Bank" • Add a 19: non-medical grade to the x-ray boom (requires isolated power) • 15" or 17" DC Powered Medical Grade Monitor mounted on the patient exam table • 19" Monitor mounted on an additional boom (requires isolated power)	
User Controls	Control Console • Custom control panel that can be placed in control room or mounted bedside Touch Pad • Custom touch pad that is mounted bedside Joy Stick • Custom joystick that can be mounted bedside	SAME
Signal Processing	Base Band (identical custom PCI boards used)	SAME
FFR	Through identical custom PCI board	SAME
iFR®	Through identical custom PCI board (same custom PCI board as used for FFR)	SAME
Inputs	- 100-240 VAC 50/60Hz Power - Catheter/PIM connection - ECG. - Aortic high-level (from hemodynamic system) - Ethernet (for DICOM Worklist) - USB (for control devices) - PS2 (for control devices) - Touchpad	SAME

Attribute/Feature	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System iFR Modality – K133323 (Predicate Device)	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System (Subject Device)
	- Joystick	
Outputs	- Monitor display: 1280 x 1024 resolution - 19" Monitor - 19" Boom Monitor - 17" Bedside Monitor - Printer	SAME
Patient Interface Module (PIM)	Compatible with Digital IVUS, Rotational IVUS, FFR Pimmette	SAME
Connection to PIMs	Via direct connection to CPU or Connection Box	SAME
Accessories and Peripherals	Bedside Touchpad Controller, Joystick Controller, Connection Box, Control Console	SAME
Imaging Specifications	Imaging boards and software	SAME
FFR Software (includes iFR Modality)	FFR Software Version v2.3	FFR Software Version v2.5 (cleared in K170133)

VII. Performance Data

The subject device is the same as the currently marketed predicate device. There are no changes to the pressure measurement wires for collection of data using the iFR® Modality. Performance data establishing the electrical safety and electromagnetic compatibility (EMC) of the device was previously reviewed in K133641 and K140291.

VIII. Clinical Data

Clinical evidence suggests the adoption of a dichotomous cut-point for Instantaneous Wave-free Ratio (iFR) guidance in coronary revascularization decision-making rather than the use of a hybrid approach as was previously documented in the Volcano FFR and iFR Modality Operator's Manual.

The clinical data submitted to support the proposed modifications to the indications is documented in the ADVISE II, DEFINE-FLAIR and iFR SWEDEHEART studies. The ADVISE II study demonstrated that

an iFR cut-point of 0.89 matches best with an FFR ischemic cut-point of 0.80 with a specificity of 87.8% and sensitivity of 73.0% (C statistic: 0.90 [95% confidence interval (CI): 0.88 to 0.92, $p < 0.001$]).[1]

The use of this dichotomous cut-point for iFR-guided revascularization was compared to FFR-guided revascularization in two large prospective randomized controlled trials.[2,3] DEFINE-FLAIR (Functional Lesion Assessment of Intermediate Stenosis to Guide Revascularization) enrolled 2492 patients with coronary artery disease in a 1:1 ratio to undergo revascularization using either FFR or iFR-guidance. The second study, iFR-SWEDEHEART (Instantaneous Wave-free Ratio versus Fractional Flow Reserve in Patients with Stable Angina Pectoris or Acute Coronary Syndrome) was similar; it enrolled 2017 patients with coronary artery disease included in the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). The registry contains data on patients from all 30 coronary intervention centers in Sweden plus a single site in Iceland.

Both studies had a primary end-point that was the composite rate of all-cause mortality, non-fatal myocardial infarction or unplanned revascularization within 12 months after the index procedure. The non-inferiority margin was 3.4 in DEFINE-FLAIR, and 3.2 in iFR-SWEDEHEART. Both studies met their respective primary endpoint by demonstrating non-inferiority at 12 months:

DEFINE-FLAIR:	6.8% (iFR) vs 7.0% (FFR); D = -0.2%; 95% CI, -2.3 to 1.8; P<0.001
iFR-SWEDEHEART:	6.7% (iFR) vs 6.1% (FFR); D = 0.7; 95% CI, -1.5-2.8, P=0.007

Both studies also demonstrated a significant reduction in adverse effects associated with the adenosine-mediated hyperemia required for FFR-guidance. 68.3% of patients in the FFR arm of iFR-SWEDEHEART reported chest discomfort, while only 3.0% of patients in the iFR arm reported any chest discomfort (P<0.001). Similarly, DEFINE-FLAIR patients in the FFR group reported adverse procedural signs or symptoms in 30.8% of cases compared to 3.1% in the iFR group (P<0.001).

The iFR guided procedures demonstrated a significant reduction in acute adverse signs or symptoms associated with the adenosine-mediated hyperemia required for FFR. The use of iFR in stable ischemic heart disease is now considered appropriate by the major American cardiology societies. A hybrid iFR-FFR strategy is thus outdated.

[1] Escaned J, Echavarria-Pinto M, Garcia-Garcia HM, et. al. Prospective Assessment of the Diagnostic Accuracy of Instantaneous Wave-Free Ratio to Assess Coronary Stenosis Relevance: Results of ADVISE II International, Multicenter Study (ADenosine Vasodilator Independent Stenosis Evaluation II). JACC Cardiovasc Interv. 2015 May;8(6):824-33.

[2] Davies JE, Sen S, Dehbi H-M, et. al. Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI. N Engl J Med. 2017 May 11;376(19):1824-1834.

[3] Götberg M, Christiansen EH, Gudmundsdottir IJ, et al. Instantaneous Wave-free Ratio versus Fractional Flow Reserve to Guide PCI. N Engl J Med. 2017 May 11;376(19):1813-1823.

IX. Conclusions

Based upon the information submitted in this premarket notification 510(k), the Volcano s5™/s5i/CORE/CORE™ Mobile Precision Guided Therapy System is substantially equivalent to the currently marketed predicate devices.