DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2017

Philips Volcano
Elaine Alan
Regulatory Affairs Specialist
3721 Valley Ctr. Dr.
San Diego, California 92130

Re: K170133
Trade/Device Name: FFR v2.5
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO
Dated: April 21, 2017
Received: April 24, 2017

Dear Elaine Alan:

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,

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)*
K170133

Device Name

FFR v2.5

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: January 16, 2017

Manufacturer:
Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670
Establishment Registration Number: 2939520

Primary Contact Person:
Elaine Alan
Regulatory Affairs Specialist
Phone: (858) 764-1281
E-mail: elain.alan@philips.com

Device:	Trade Name:	FFR v2.5
	Classification Name:	Ultrasonic Pulsed Echo Imaging System
	Classification Regulation:	21 CFR, Part 892.1560
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	Product Code: IYO
Predicate Device:	Trade Name:	iFR Scout (FFR v2.4)
	Manufacturer:	Volcano Corporation
	510(k) Clearance:	K150441 (March 20, 2015)
	Classification Name:	Ultrasonic Pulsed Echo Imaging System
	Classification Regulation:	21 CFR, Part 892.1560
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	Product Code: IYO

Device description:

The FFR v2.5 software is used to obtain pressure measurements and is installed on the Volcano s5/CORE Systems. These systems are a multi-modality platform that provides Intravascular Ultrasound (IVUS) Imaging, Fractional Flow Reserve (FFR) pressure measurements, and Instant Wave-Free Ratio (iFR) pressure measurements. Pressure measurements are obtained through the use of pressure guide wires. Real-time image visualization of patient anatomy during procedures.

FFR pressure measurements are obtained during fluoroscopic procedures after the administration of a hyperemic agent such as adenosine. iFR pressure measurements do not require the use of a hyperemic agent. 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 pressure reading is calculated after administration of a hyperemic agent.

Modifications to the software include the ability to take FFR and iFR measurements without relying on ECG and allowing for broadcast FFR and iFR measurement data to a third party system over a network.

Indications for Use:

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

Based on the information provided above, the FFR v2.5 software is considered substantially equivalent to the currently marketed and predicate device, the iFR Scout (FFR v2.4 software) in terms of Indications for Use.

Technological characteristics:

The FFR v2.5 software has the same technological characteristics compared to the predicate device. Modifications implemented in the FFR v2.5 software include:

- ECG-less Cardiac Cycle Detection
- FM Broadcast

The differences between the FFR v2.5 software and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) submission, the FFR 2.5 software is considered substantially equivalent to the currently marketed predicate iFR Scout (FFR v2.4) in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the FFR v2.5 software and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance documents:

- IEC 62304 *Medical device software – Software life cycle processes* (Edition 1.0, 2006). FDA/CDRH recognition number 13-32.

Software verification testing has been performed to cover system level requirements as well as risk control measures. Results demonstrated that all executed tests were passed.

Non-clinical validation testing has been performed to cover the intended use, commercial claims, service, user needs, effectiveness of safety measures and instructions for use.

Therefore, the FFR v2.5 software is substantially equivalent to the currently marketed iFR Scout (FFR v2.4) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The FFR v2.5 software did not require clinical data since substantial equivalence to the currently marketed predicate device was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

These attributes demonstrated that the clinical performance of the modified device is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion:

The FFR v2.5 software is substantially equivalent to the currently marketed predicate device, the iFR Scout (FFR 2.4) in terms of indications for use, technological characteristics and safety and effectiveness.

The modification to the FFR v2.5 software is within the controls and predetermined specifications. Additionally, non-clinical performance tests provided in this 510(k) premarket notification demonstrated substantial equivalence to the predicate device and ensured that the modification is properly introduced; verification and validation testing was conducted to ensure the proper introduction of the modifications; conformance to IEC standards and guidance documents were provided. The tests performed support substantial equivalence of the modified device and demonstrate that the FFR v2.5 software is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.