K123898

510(k) SUMMARY

JAN 14 2013

The 510(k) Summary is submitted as required by section 807.92(a)

SPONSOR:	Volcano Corporation 2870 Kilgore Road Rancho Cordova, CA 95670
CONTACT/SUBMITTER:	Jwala Jawharkar Regulatory Affairs Specialist 2870 Kilgore Road Rancho Cordova, CA 95670 Tel. (916) 281-2925 Fax: (916) 638-8112
DATE OF SUBMISSION:	December 17, 2012
DEVICE:	Volcano s5™/s5i® Intravascular Ultrasound Imaging System
Trade Name:	Volcano s5™/s5i® Intravascular Ultrasound Imaging System
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:	Volcano s5™/s5i® Intravascular Ultrasound Imaging System (K111706 and K113486)

DEVICE DESCRIPTON:

The Volcano s5™/s5i® Intravascular Ultrasound Imaging and Pressure Systems are currently available in 2 configurations: (1) a tower or a portable model where the device can be moved from one room to another, and (2) an integrated model, where the system is integrated into the catheterization (cath) lab. Both tower and integrated configurations of the Volcano s5/s5i Imaging and Pressure system offer: (1) the Intravascular Ultrasound (IVUS) imaging mode and (2) the pressure mode.

When operating the IVUS mode, the system console gathers and displays high-resolution intraluminal images that can be analyzed both quantitatively and qualitatively. When operating in pressure mode, the system acquires intraluminal data from a pressure guidewire while simultaneously taking aortic pressure data from the established ECG/EKG catheterization lab equipment. Catheters and guidewires are connected to the system via the Patient Interface Modules (PIMs).

INDICATIONS FOR USE:

The Volcano s5™/s5i® Series Intravascular Imaging and Pressure 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 wall structures. The pullback feature of the PIMr withdraws the imaging core within the protective sheath for a maximum of 15 cm.

COMPARISON OF CHARACTERISTICS:

The proposed device is identical to the currently marketed device except for the change to the Rotational IVUS software feature designed to offer users the option to select from multiple imaging options with the same Revolution® catheter. This allows the user to select the imaging option preference that he/she prefers to visualize blood speckle and tissue along the lumen border. The proposed device shares the same intended use, same design characteristics, and the same fundamental scientific technology as that of the predicate device.

PERFORMANCE DATA:

Applicable testing was performed as required by the Quality System to evaluate the software modification to the Volcano s5/s5i Intravascular Imaging and Pressure System. The following tests were conducted:

- Software Verification and Validation
- Image Assessment
- Use Validation

The test results were found to be acceptable by the respective test plans and protocols. The changes to the device involve modifications to the Rotational IVUS software feature. Biocompatibility and sterilization testing was not required for the device modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 14, 2013

Mr. Jwala Jawharkar
Regulatory Affairs Specialist
Volcano Corporation
2870 Kilgore Road
RANCHO CORDOVA, CA 95670

Re: K123898
Trade/Device Name: Volcano s5™/s5i® Intravascular Ultrasound Imaging and Pressure System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, DSK, and DSA
Dated: December 17, 2012
Received: December 18, 2012

Dear Mr. Jawharkar:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123898

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123898