510(k) SUMMARY

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

Submitter Name:	Volcano Corporation
Contact Person:	Mamta Vats Regulatory Affairs Specialist
Address:	2870 Kilgore Road Rancho Cordova, CA 95670
Phone Number:	916-231-4515
Fax Number:	916-638-2647
Date Prepared:	08/04/2008
Device Trade Name:	**Volcano s5/s5i Series Intravascular Imaging and Pressure Systems** **ComboMap Pressure and Flow System**
Device Common Name:	**Ultrasonic imaging system** **Intravascular Blood Pressure and Blood Flow System**
Classification Name, Number, Product Code:	892.1560 Ultrasonic pulsed echo imaging system, II, IYO 870.2100 Cardiovascular blood flow meters, II, DPW 870.1110 Blood Pressure Computer, II, DSK 870.2900 Patient Transducer and Electrical Cable, II, DSA

Predicate Device Table

Predicate System Name	Predicate System 510(k) Clearance	Current Catalog Numbers
Volcano s5/s5i Series Intravascular Imaging and Pressure System	K071554	s5/807300-001 s5i/807400-001
ComboMap® Pressure and Flow System	K041134	6800

Other prior predicates:
WaveMap cleared under K965140; SmartMap cleared under K021219; ColorFlo Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K963290 on August 6, 1997; the Resolve Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K965223 on June 29, 1998, the InVision Imaging System cleared under K031148 on May 28, 2003.

NOTE: Volcano Therapeutics, Inc. (now Volcano Corporation) purchased the assets of JOMED Inc. on July 21, 2003. JOMED Inc. purchased Endosonics Corporation.

Device Description:
Volcano s5/s5i Series Intravascular Imaging and Pressure System
This system is available in 3 configurations; 1) a tower or portable model, 2) an integrated model, and 3) an integrated model with communication capabilities with 3rd party angiography equipment.

General Operation Overview
When operating in IVUS mode, the system console gathers and displays high-resolution intraluminal images that can be analyzed both qualitatively and quantitatively. In addition to supplying diagnostic information, the Volcano s5/s5i system is an adjunct to interventional therapies, such as balloon angioplasty. With ChromoFlo® (not available with Revolution catheter), a two-dimensional color map of relative blood velocities is overlaid on the grayscale image, providing additional information for vessel analysis. The In-Line Digital feature displays a two-dimensional, longitudinal view of the vessel. The angle of the longitudinal cut can be varied around the full 360 degrees.

When operating in pressure mode, the system acquires intraluminal data from the pressure guidewire (SmartWire II and ComboWire II) while simultaneously taking aortic pressure data from the established ECG/EKG catheterization lab equipment. In conjunction with the

procedure, the system measures pressure and calculates pressure differences between the aortic pressure and the SmartWire/ComboWire pressure transducer typically located distal to the vascular lesion and calculates the fractional flow reserve (FFR).

ComboMap Pressure and Flow System

The ComboMap™ Pressure and Flow System is a computer-controlled (PC-based) instrument, which processes the information it receives from the transducer mounted in a Volcano Corporation SmartWireR Pressure Guide Wire (K021219), Volcano Corporation FloWireR Doppler Guide Wire (K905411, K912776, K921563, K972762), and/or external inputs, to produce real-time blood pressure and/or blood flow velocity. There are 4 modes available to operate from and switch between on the ComboMap™; System, Pressure, Flow, and Combo. Depending on the mode and setup selections made, the computer screen displays a combination of waveforms, measured values, and calculated parameters on the display screen. Additional controls also appear on the display screens.

In the Pressure Mode, the ComboMap™ provides digital and graphical readout of mean aortic pressure from a guide catheter, mean SmartWireR pressure, and a calculated parameter, such as gradient or fractional flow reserve (FFR), and one of six (6) selected waveforms. The ComboMap™ also supplies an analog output of the SmartWireR pressure for display on a conventional physiologic monitoring system.

In the Flow Mode, there are two (2) operating modes to measure blood flow velocity in either coronary or peripheral vessels. This is because in coronary arteries, maximum blood flow velocity occurs predominantly during diastole and in peripheral arteries, maximum flow occurs during systole. The ComboMap™ displays the waveforms selected and provides digital readout of calculated parameters such as average peak velocity (APV) and flow reserve.

The ComboMap™ System offers the unique ability to simultaneously display pressure and velocity waveforms using the Combo Mode. Layout of the Pressure and Doppler display as well as selected waveforms is customized by the user allowing a combination of any of those described above in Pressure Mode and Flow Mode.

Intended Use:

Volcano s5/s5i series Intravascular Imaging and Pressure System

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.

ComboMap Pressure and Flow System
The ComboMap 6800 System measures intravascular blood pressure and/or blood flow velocity in all blood vessels, including the coronary and peripheral arteries, during diagnostic and/or interventional procedures.

Performance Data:
A risk analysis was conducted according to 803475-001 *Risk Management* which was written to comply with ISO 14971 and IEC 60601-1-4 as specific risk management standards. Also taken into consideration in this procedure are 21 CFR 820.30 and the Medical Device Directive of the European Union (93/46/EEC). Applicable testing was performed as required by the Quality System to evaluate the modifications to the Volcano s5/s5i Intravascular Imaging and Pressure System and ComboMap Pressure and Flow System. The test results were found to be acceptable as required by the respective test plans and protocols.

Conclusion:
The discussion and data presented in this 510(k) and conformance with Design Controls and the Quality System Regulations establishes the Volcano s5/s5i Series Intravascular Imaging and Pressure System and ComboMap Pressure and Flow System to be substantially equivalent for its intended use to the predicate devices listed in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Volcano Corporation
c/o Ms. Mamta Vats
Regulatory Affairs Specialist
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K082229
Trade/Device Name: s5/s5i Series Intravascular Imaging and Pressure System and ComboMap Pressure and Flow System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, IYO
Dated: September 9, 2008
Received: September 11, 2008

Dear Ms. Vats:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

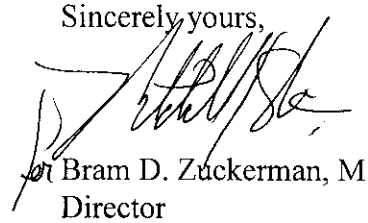
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K082229

Device Name: Volcano s5/s5i Series Intravascular Imaging and Pressure System

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.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 10/8/08
Division of Cardiovascular Devices

510(k) Number K082229

(Posted November 13, 2003)

Statement of Indications for Use

510(k) Number (if known): K082229

Device Name: ComboMap™ Pressure and Flow System

Indications for Use:

ComboMap™ Pressure and Flow System is a multi-mode system intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure and/or blood flow velocities during diagnostic angiography and/or interventional procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.19)

OR

Over-the-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082229