SECTION 8 - 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c)

The assigned 510(k) number is: **K042188**

Name and Address of Applicant
Volcano Therapeutics, Inc.
2870 Kilgore Road
Rancho Cordova, CA 95670
916-638-9404 phone
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Primary Contact:
Lorry Huffman
lhuffman@volcanotherapeutics.com

Preparation Date: August 4, 2004/October 8, 2004

Trade name: Volcano IVUS System

Common names: Ultrasound Pulsed Echo Imaging System
Picture Archiving and Communications Systems

Predicate devices:

- K022824, TomTec Imaging Systems, GmbH, Cardio-View device
- K001592, TomTec Imaging Systems, GmbH, EchoCom device

Description of the new device:

The Volcano Therapeutics, Inc. Volcano IVUS System is a combination of proprietary hardware and software and a phantom normalization device.

The hardware portion consists of a high-speed computer, with monitor, specifically built for use in medical institutions; high-speed analog-to-digital conversion circuitry and proprietary gating circuitry. The system is connected to the output connectors of conventional IVUS systems and the ECG system using typical cabling. The IVUS radiofrequency output is used directly by the Volcano IVUS System and the ECG output is used to gate or time the collection / recording of the IVUS signal.

The software that provides the user interface is Windows 2000 Professional. The Volcano IVUS System applications presently exist in two pieces. The first is the data acquisition package, IVUSLabRF. This application contains the drivers that control the Gage A/D converter card which digitizes the RF data from the IVUS console. It also manages the joining of the data from individual scans that constitute a "slice".

The second software program is called IVUSLabVH. This program analyzes each of the slices. These images are visually reviewed and the control points are manually adjusted until they appear in the proper location on the vessel inner and outer borders. Once all the control points have been properly located the software produces a set of data files called "snaxel" files which define the coordinates of the control points. The black and white IVUS files and the snaxel files are loaded into the IVUSLabVH software which processes the data to produce the five color bit mapped Volcano IVUS image files.

The system requires the use of a "phantom" to "normalize" the conventional IVUS output. The phantom is a small piece of acrylic material machined to allow placement over the IVUS catheter distal tip.

Intended use / Indications for Use:

The Volcano Therapeutics, Inc. Volcano IVUS System is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano 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.

Technological Characteristics and comparison to predicate devices:

The Volcano IVUS System has the same technological features and characteristics as the two listed predicate devices. Both of these devices are intended to be used as an adjunct to conventional angiographic and IVUS procedures. Both of these devices are used to evaluate features of the human heart and/or vasculature and visualize internal boundary features.

Semi-automatic border detection and color coding information are features that are found on predicate devices and the Volcano IVUS System.

Each of the technological characteristics found in the Volcano IVUS System is similar or identical to the specified predicate devices. As a result, Volcano Therapeutics, Inc. believes that the combination of the two commercially-available predicate devices supports the claim of substantial equivalence to the Volcano IVUS System consistent with the 510(k) regulatory paradigm.

Performance / test data:

The Volcano IVUS System complies with IEC 60601-1 and IEC 60601-1-2 as verified by independent test facilities. The Volcano IVUS System also displays the UL mark. The Volcano IVUS System software was verified and validated per FDA guidance documents and the System passed internal tests per internal company procedures.

Conclusions:

The Volcano IVUS System has the same intended use as the predicate devices. The Volcano IVUS system also includes similar or identical technical features and characteristics as the predicate devices. Additionally, testing and validation exercises have produced results consistent with design input requirements. Therefore, the Volcano IVUS system does not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2004

Volcano Therapeutics, Inc.
Ms Lorry Huffman
Director, Regulatory Affairs and Quality Assurance
2870 Kilgore Road
Rancho Cordova, CA 95671

Re: K042188
Trade Name: Volcano IVUS System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: II (two)
Product Code: IYO
Dated: August 10, 2004
Received: August 12, 2004

Dear Ms. Huffman:

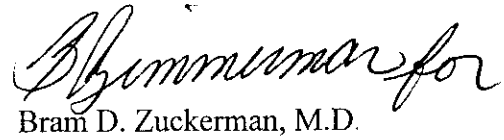
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

SECTION 9 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K042188**

Device Name: Volcano IVUS System

Indications for Use:

The Volcano Therapeutics, Inc. Volcano IVUS System is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano 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.

(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 K042188