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Volcano Therapeutics, Inc.
April 29, 2004ComboMap™ Pressure and Flow System
Special 510(k)**510 (K) Summary****ComboMap™ Pressure and Flow System****Date Prepared:** April 29, 2003**Submitted by:** Volcano Therapeutics, Inc.
2870 Kilgore Rd.
Rancho Cordova, CA 95670**Contact person:** Lorry W. Huffman
Regulatory Affairs Manager**Phone number:** (916) 638-9404 or (800) 228-4728 ext. 404**Facsimile number:** (916) 638-8112**Device Name:** ComboMap™ Pressure and Flow System

Classification name:	<u>Class</u>
870.2100 – Cardiovascular blood flow meters	II
870.1110 – Blood Pressure Computer	II
870.2900 – Patient Transducer and Electrical Cable	II

Predicate Device:

SmartMap ^R Pressure System	K021219
WaveMap ^R Pressure System	K965140
FloMap ^R Doppler Flow System	K921563

Volcano Therapeutics Inc. purchased the assets of JOMED Inc. who had previously purchased Cardiometrics, Inc. under which K021219, K965140 and K921563 were filed.

Device Description:

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 Therapeutics SmartWire^R Pressure Guide Wire, Volcano Therapeutics FloWire^R Doppler Guide Wire, 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 SmartWire^R pressure, and a calculated parameter, such as gradient or fractional flow reserve (FR), and one of

six (6) selected waveforms. The ComboMap™ also supplies an analog output of the SmartWire^R 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*.

Depending on the clinicians' preference, the physician has the option of using a pressure guide wire (SmartWire^R), a flow guide wire (FloWire^R) or both. By using these guide wires from Volcano Therapeutics, the physician can measure pressure and/or flow velocity.

The pressure and flow guide wires are marketed under separate 510(k)'s;
SmartWire^R K021219
FloWire^R K905411, K912776, K921563, K972762

Wires that can currently be used with the ComboMap are as follows:
SmartWire 6400, 6400J, 6403, 6403J, 6413, 6413J (BrightWire name is used in certain European countries due to trademark issues 7400, 7400J, 7403, 7403J)
FloWire 1400, 1400J, 1401, 1401J, 1403, 1403J, 1404, 1404J, 1413, 1413J

Model Numbers and Accessories:

ComboMap™ Unit	6800
ComboMap™ Patient Cable (PIM)	6805
ComboMap™ Remote Control	6810
ComboMap™ Printer	6815
ComboMap™ Cart	6820
Printer Paper	803545-001
Printer Power Supply	803933-001

Intended 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.

Device Technological Characteristics and Comparison to Predicate Device:

Currently pressure and flow velocity are measured with separate guide wires (SmartWire^R or FloWire^R), connected to separate systems (WaveMap^R or FloMap^R). The ComboMap™ combines the functionality of both technologies in one system. Signal processing, measurement modalities and instrument connections are the same as the predecessor instruments. The intended use and the fundamental scientific technology of the SmartMap^R, WaveMap^R, and FloMap^R have not been altered but are combined together in the ComboMap™.

Performance Data:

Applicable testing was performed to evaluate the ComboMap™ Pressure and Flow System. The test results were found to be acceptable as required by the respective test plans and protocols.

Conclusion:

The ComboMap™ Pressure and Flow System has the same intended use and utilizes the same fundamental scientific technology as that of the predicate devices. There are no new questions raised regarding safety and efficacy. The information provided in this Special 510(k) submission along with the *Declaration of Conformity with Design Controls* support a determination of substantial equivalence of the ComboMap™ Pressure and Flow System to the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Volcano Therapeutics, Inc.
c/o Ms. Lorry W. Huffman
Manager, Regulatory Affairs
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Re: K041134

Trade/Device Name: ComboMap Pressure and Flow System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II
Product Code: OBJ
Dated: April 29, 2004
Received: April 30, 2004

Dear Ms. Huffman:

This letter corrects our substantially equivalent letter of June 2, 2004.

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 (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.

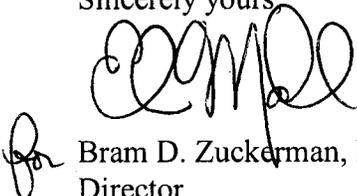
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 (240) 276-4080. 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 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/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

510(k) Number (if known): K041134

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.

Shelley Ozyal
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K041134

(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 _____