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510(k) SUMMARY

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

Submitter Name:	Volcano Corp.
Contact Person:	Jennifer M. Motto Associate, Regulatory Affairs
Address:	2870 Kilgore Road Rancho Cordova, CA 95670
Phone Number:	916-638-9430
Fax Number:	916-638-8112
Date Prepared:	August 26, 2005
Device Trade Name:	**In Vision Gold with SpinVision**
Device Common Name:	Intravascular Ultrasound Imaging System
Classification Name, Number, Product Code:	Ultrasonic pulsed echo imaging system 21 CFR 892.1560, Product Code: IYO

Predicate Device:
In-Vision™ Imaging System cleared under K031148 on May 28, 2003; with specific aspects compared to Automatic Pullback Device cleared under K962293 on September 16, 1996; Galaxy Intravascular Ultrasound System, Model 150 cleared under K980851 on April 22, 1998.

Device Description:
SpinVision is an accessory to the In-Vision Gold Imaging System that enables the Revolution 45MHz Rotational Imaging Catheter to generate intravascular ultrasonic images. The primary components of the SpinVision accessory consist of the Patient Interface Module (PIMr), upgraded Analog/Digital/Sigma board, and the host software. The ability to perform an automatic or manual pullback is integrated into the PIMr. An RFID transmitter within the rotational catheter sends a low frequency signal to the PIMr allowing it to recognize the name and serial number of the catheter.

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Intended Use:

Qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral 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 15cm.

Performance Data:

Applicable testing was performed to evaluate the SpinVision accessory to the In-Vision Imaging System. The test results were found to be acceptable as required by the test plans and protocols.

Conclusion:

The testing reported in this 510(k) establishes the device is safe and effective for its intended use and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2005

Volcano Corporation
c/o Ms. Jennifer M. Motto
Regulatory Affairs Associate
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Re: K052348
Trade Name: In Vision Gold with Spin Vision, Model 891 SV
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO
Dated: August 26, 2005
Received: August 29, 2005

Dear Ms. Motto:

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 (240) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

Indications for Use

510(k) Number (if known): K052348

Device Name:

In Vision Gold with SpinVision

Indications for Use:

Qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral 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 15cm.

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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052348