



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 19, 2015

Volcano Corporation
Mary Stanners
Regulatory Affairs Specialist
3721 Valley Centre Drive, Suite 500
San Diego, California 92130

Re: K152829

Trade/Device Name: Visions PV.014P RX Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: November 3, 2015
Received: November 4, 2015

Dear Mary Stanners:

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

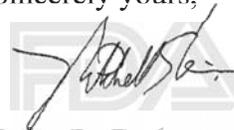
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large "FDA" watermark.

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)

K152829

Device Name

Visions® PV.014P RX Digital IVUS Catheter

Indications for Use (Describe)

The Visions® PV.014P RX Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in the cerebral vessels.

The Visions® PV.014P RX Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

SPONSOR: Volcano Corporation
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San Diego, CA 92130

CONTACT/SUBMITTER: Mary Stanners
Regulatory Affairs Specialist
Volcano Corporation
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130
Tel: (858) 764-1296
mstanners@volcanocorp.com

DATE OF SUBMISSION: November 16, 2015

DEVICE:

Trade Name: Visions[®] PV.014P RX Digital IVUS Catheter

Common Name: Diagnostic Intravascular Catheter
Diagnostic Ultrasound Transducer

Classification and Product Codes:

| CFR Number | Class | Product Code |
|---|-------|--------------|
| 21 CFR 870.1200 Diagnostic Intravascular Catheter | II | OBJ |
| 21 CFR 892.1570 Diagnostic Ultrasound Transducer | II | ITX |

PREDICATE DEVICE:

Trade Name: K143701-Eagle Eye Platinum Catheter (EEP), Eagle Eye Platinum Short Tip (EEP-ST), Visions[®] PV.014 Platinum (PV.014P)

Common Name: Diagnostic Intravascular Catheter
Diagnostic Ultrasound Transducer

Classification and Product Codes:

| CFR Number | Class | Product Code |
|---|-------|--------------|
| 21 CFR 870.1200 Diagnostic Intravascular Catheter | II | OBJ |
| 21 CFR 892.1570 Diagnostic Ultrasound Transducer | II | ITX |

Special 510(k): Modification of the Volcano PV.014P RX Catheter

DEVICE DESCRIPTION:

The PV .014P RX Catheter incorporates a cylindrical ultrasound transducer array located near the distal tip of the Catheter. The array radiates acoustic energy into the surrounding tissue and detects the subsequent ultrasonic echoes. The information from the echoes is used to generate real-time images of the coronary or peripheral vessels.

The term RX has been added to the PV.014P Catheter to identify it as a rapid exchange catheter. The rapid exchange feature has not changed from the currently marketed PV.014P Catheter. Volcano is adding the term RX to the name to clearly identify the catheter as rapid exchange.

The PV .014P RX Catheter utilizes an internal lumen that allows the catheter to track over a 0.014" (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the Catheter tip. The device is introduced either percutaneously or via surgical cut down into the vascular system.

The PV .014P RX Catheter may be used with the Volcano s5™, Volcano s5i™, Volcano CORE Mobile, and Volcano CORE imaging systems. The device is designed to work with Volcano VH IVUS system software v1.2 or higher. This catheter will not operate if connected to any other imaging system.

The modified PV.014P Catheter (PV.014P RX) has a stiffer core to help improve device deliverability. The stiffer core wire provides increased “pushability” while maintaining the same trackability as the currently marketed PV.014P Catheter. In order to increase “pushability”, the size of the core wire within the proximal shaft of the catheter was made with a larger OD. The proximal end was increased while keeping the distal end diameter the same. The modified PV.014P Catheter (PV.014P RX) with stiffer core utilizes the same current manufacturing processes, equipment and materials as the currently marketed device.

The modified PV.014P Catheter (PV.014P RX) has the same intended use, same fundamental scientific technologies and the indications for use are identical to the currently marketed PV.014P. The modified PV.014P Catheter (PV.014P RX) was tested and verified. The modified PV.014P Catheter (PV.014P RX) does not raise any new questions of safety or effectiveness and the modified device is substantially equivalent to the currently marketed PV.014P Catheter. Therefore, Volcano concludes that the modification is substantially equivalent to the currently marketed PV.014P Catheter.

INDICATIONS FOR USE:

The Indications For Use remain the same and is as follows:

The Visions® PV.014P RX Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in the cerebral vessels.

The Visions® PV.014P RX Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The modification made to the PV.014P Catheter does not affect the intended use of the device or technologies and it does not alter the fundamental scientific technologies. The indications for use are identical to those of the currently marketed device. The modified catheter is substantially equivalent to currently marketed device.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the modified device. Bench testing was conducted against known standards or product specification and evaluated the following:

- Cross and Re-Cross
- Insertion and Recovery (Trackability)
- Buckling.
- Signal Processing

Cross/Re-Cross and Insertion/Recovery tests measured the force required to advance and retract the catheter. Cross/Re-Cross utilizes a simulated lesion through a tortuous block. Insertion/Recovery testing was completed without a simulated lesion to demonstrate the ability of the catheter to move through the vasculature. The results demonstrated that there is no statistically significant difference between the subject device and control device for Cross/Re-Cross and Insertion/Recovery (Trackability).

Buckling was conducted in accordance with FDA's Guidance Document "*Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*" which recommends mechanical testing to include buckling. Buckling is a measure of the rigidity of the catheter. The results demonstrated acceptable rigidity of the catheter.

Signal processing provided a quantitative and qualitative image assessment. The results demonstrated that the change did not affect imaging.

All bench testing was successfully completed. The successful completion of performance testing concluded that the modified PV.014P Catheter (PV.014P RX) is substantially equivalent to the currently marketed PV.014P Catheter.

For this change (core wire diameter change from 0.016" to .018"), the Standards as described in Attachment F FDA 3654 forms of submission) used were the following:

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|----------------------|--|
| BS EN ISO 13485:2012 | Medical Devices Quality Management System Requirements for Regulatory Purposes |
| ISO 14971:2012 | Medical Devices - Application of Risk Management to Medical Devices |