JUN 2 1 2013

510(k) SUMMARY

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

SPONSOR:	Volcano Corporation 2870 Kilgore Road Rancho Cordova, CA 95670
CONTACT/SUBMITTER:	Jwala Jawharkar Regulatory Affairs Specialist Volcano Corporation 2870 Kilgore Road Rancho Cordova, CA 95670 Tel: (916) 281-2925 Fax: (916) 638-8112
DATE OF SUBMISSION:	May 3, 2013
DEVICE:	Volcano Verrata™ Pressure Guide Wire
Trade Name: Common Name: Classification:	Verrata™ Pressure Guide Wire Pressure Guide Wire Class II Device 21 CFR Part 870.1330 Catheter guide wire (DQX) 21 CFR Part 870.2870 Catheter tip pressure transducer (DX0)
PREDICATE DEVICE:	Volcano PrimeWire PRESTIGE® Plus Pressure Guide Wire
DEVICE DESCRIPTION:	The Verrata™ Pressure Guide Wire is a steerable guide wire with a pressure transducer mounted 3 cm proximal to the tip. The Verrata guide wire measures pressure when used with the SmartMap, s5 Family and ComboMap systems. The Verrata guide wire has a diameter of 0.014" (0.36 mm) and is available in lengths of 185 cm or 300 cm and also in straight or pre-shaped J tips. The Verrata guide wire is packaged pre-connected to the connector with a torque device to facilitate navigation through the vasculature.
INDICATIONS FOR USE:	The Verrata™ Pressure Guide Wire device is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

COMPARISON OF CHARACTERISTICS:

The modified device is substantially equivalent to the currently marketed PrimeWire PRESTIGE® Plus device. Both devices are Pressure Guide Wires consisting of a wire and connector. The modified Verrata™ Pressure Guide Wire is offered in two lengths and two tip configurations for a total of 4 models, identical to the currently marketed device. The outer diameter and working length are identical for both the predicate and modified devices. The indications for use are identical for both devices. The only difference lies in a modification to the connector.

PERFORMANCE DATA:

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

- Visual Inspection
- Dimensional Verification
- Wire Connection Durability
- Tensile Strength
- Connector Resistance

Biocompatibility testing was not conducted on the device as the direct and indirect blood-contacting materials are identical to those used in the predicate device.

Completion of these tests concluded the Verrata™ Pressure Guide Wire is substantially equivalent to the currently marketed PrimeWire PRESTIGE® Plus Pressure Guide Wire.

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

June 21, 2013

Volcano Corporation
Jwala Jawharkar
Regulatory Affairs Specialist
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K131288
Trade/Device Name: Verrata™ Pressure Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX, DXO
Dated: May 22, 2013
Received: May 23, 2013

Dear Jwala Jawharkar:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman -S

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

Indications for Use Statement

510(k) Number (if known) K131288

Device Name Verrata™ Pressure Guide Wire

Indications for Use The Verrata™ Pressure Guide Wire is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

Prescription Use ___X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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