DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 20, 2016

Volcano Corporation
Brian Park
Regulatory Affairs Manager
3721 Valley Centre Drive, Suite 500
San Diego, California 92130

Re: K161887
Trade/Device Name: Verrata PLUS Pressure Guide Wire, 185 cm Straight Tip;
Verrata PLUS Pressure Guide Wire, 185 cm J-tip;
Verrata PLUS Pressure Guide Wire, 300 cm Straight Tip;
Verrata PLUS Pressure Guide Wire, 300 cm J-tip
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DXO
Dated: August 19, 2016
Received: August 22, 2016

Dear Brian Park:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161887

Device Name
Verrata® PLUS Pressure Guide Wire

Indications for Use *(Describe)*
The Verrata® PLUS 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.

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.

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510(K) SUMMARY

SPONSOR:

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CONTACT/SUBMITTER:

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DATE PREPARED:

July 8, 2016

DEVICE:

Volcano Verrata® PLUS Pressure Guide Wire

TRADE NAME:

Verrata® PLUS Pressure Guide Wire

COMMON NAME:

Pressure Guide Wire

CLASSIFICATION:

21 CFR 870.1330
DQX: Catheter Guide Wire
Class II Device

21 CFR 870.2870
DXO: Catheter Tip Pressure Transducer
Class II Device

PREDICATE DEVICE:

Verrata® Pressure Guide Wire, K131288

Model numbers:
10185, Straight Tip, 185 cm long, 0.014" (0.036 mm) dia.
10185J, J-Tip, 185 cm long, 0.014" (0.036mm) dia.
10300, Straight Tip, 300 cm long, 0.014" (0.036 mm) dia.
10300J, J-Tip, 300 cm long, 0.014" (0.036mm) dia.

DEVICE DESCRIPTION:

The Verrata® PLUS Pressure Guide Wire (hereafter referred to as the "Verrata PLUS") is a steerable guide wire with a pressure transducer mounted 3 cm proximal to the tip. The Verrata® PLUS measures pressure when used with the SmartMap®, ComboMap®, s5 Series™, and CORE™ Series of systems. The Verrata PLUS 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 tips. The Verrata PLUS is packaged attached to the connector with a torque device to facilitate navigation through the vasculature.

INDICATIONS FOR USE:

The Verrata® PLUS 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.

COMPARISON OF CHARACTERISTICS:

Volcano Corporation made minor revisions to the currently marketed Verrata Pressure Guide Wire. The pressure sensor and its encapsulating adhesive was changed, the routing of the connector cable was changed from exiting the connector body from the bottom to exiting from the side in line with the wire, paraffin wax was added to a non-patient contacting surface inside of the connector drawer and the non-patient contacting torsion spring inside the connector is now coated with a soap solution. There are no changes to any final product or performance specifications as a result of these changes.

PERFORMANCE DATA:

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

- Visual Inspection: Sample wires and connectors were visually inspected to confirm proper routing of the cable out of the connector. Acceptance Criteria: Cable must be routed out the right side of the connector.
- Visual Inspection: Sample wires were visually inspected to confirm that the pressure sensor within the pressure housing is properly aligned, positioned and potted in place. Acceptance Criteria: The sensor adhesive is not protruding out of the housing and the sensor is not damaged or misaligned.

- Wire Outer Diameter: The maximum diameter of the sensor housing is measured with a micrometer. Acceptance Criteria: The sensor housing outer diameter must meet product specifications.
- Zero Test and Connection Durability Test: Wires with connectors were connected to a Volcano Pressure System and "zeroed". The pressure value on the screen of the System should read "0". Disconnect the wire from the connector and re-connect up to 20 times. After 20 disconnect and re-connects, verify that the wire still "zeros". Acceptance Criteria: The wire must successfully zero the first time and after 20 disconnect and re-connect cycles.
- Accuracy Test: The wire is connected to a test fixture and is placed in an air pressure chamber at 37ºC. The pressure inside the chamber is varied and the pressure reading from the wire is compared to the pressure to which the chamber is set. Acceptance Criteria: The pressure measured by the wire must meet product specifications.
- Drift Test: The wire is connected to a test fixture and placed in saline at 37ºC. The pressure reading is recorded for 10 minutes. Acceptance Criteria: The drift over 10 minutes must meet product specifications.
- Connector to Cable Tensile Test: The connector to cable connection was pull tested to assess its tensile strength. Acceptance Criteria: The tensile strength must meet product specifications.
- Biocompatibility: Biocompatibility of the raw materials in the Verrata PLUS wire were assessed per ISO 10993. Acceptance Criteria: Per ISO 10993 and test protocols.
  Direct Contact Hemolysis Acceptance Criteria: The difference between the hemolytic indices of the test article and negative control must be <2%.
  Extract In-direct Contact Hemolysis Acceptance Criteria: The difference between the hemolytic indices of the test article and negative control must be <2%.
  Latex Elisa test for Antigenic Protein Acceptance Criteria: Reporting Limit = 0.03µg/ml.
  Cytotoxicity Acceptance Criteria: A score of ≤2 indicates that the test article is not cytotoxic.

- Connector Fluid Ingress: Sample wires and connectors were connected to a Volcano Pressure System. The connector was placed on top of absorbent drapes. The System was turned on and saline was dripped on the connector while the pressure waveform was monitored on the screen of the System. After 5 minutes, the connector was flipped over. After an additional 5 minutes the recording was stopped. Verrata PLUS was compared to the Verrata. Acceptance Criteria: Stable signal time of the Verrata PLUS connector in the presence of saline is equal to or better than the stable signal time of the Verrata connector in the presence of saline.
- Device Deliverability/Compatibility: Two different heart models in a 37ºC water bath were used to assess the ability of the Verrata PLUS to support the delivery and deployment of standard interventional devices. The first model was used to assess device deliverability in simulated Left Circumflex and First Obtuse Marginal vessels. The second model was used to assess the ability of the Verrata PLUS to support the inflation of a standard balloon catheter and the deployment of a stent. Acceptance Criteria:

CONSENSUS STANDARDS

The Verrata PLUS Pressure Guide Wire complies with the following consensus standards:

The ISO 10993 series of biocompatibility standards including
ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ANSI/AAMI/ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ASTM F756 -13, Standard Practice for Assessment of Hemolytic Properties of Materials

ASTM D6499-12, Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

	ISO 14971:2007 Medical devices - Application of risk management to medical devices
CONCLUSION	Completion of all performance tests concludes that the Verrata PLUS Pressure Guide Wire is substantially equivalent to the currently marketed Verrata Pressure Guide Wire.