April 15, 2020

Volcano Corporation
Leilani Taylor
Sr. Regulatory Affairs Specialist
3721 Valley Centre Drive, Ste 500
San Diego, California 92130

Re: K210235
Trade/Device Name: Verrata PLUS Pressure Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DXO
Dated: March 15, 2021
Received: March 16, 2021

Dear Leilani Taylor:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210235

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. It can also be used to guide the positioning of a balloon dilatation catheter, as well as other interventional devices. 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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VOLCANO
PRECISION GUIDED THERAPY

K210235

This 510(k) Summary was prepared in accordance with 21 CFR 807.92 (c)

510(k) SUMMARY

SUBMITTER:	Volcano Corporation 3721 Valley Centre Drive, Ste 500 San Diego, CA 92130
CONTACT PERSON:	Leilani Taylor Regulatory Affairs Specialist Volcano Corporation 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130 Tel: (858) 720-4121
DATE PREPARED:	April 02, 2021
DEVICE NAME:	Verrata PLUS Pressure Guide Wire
COMMON NAME:	Wire, guide, catheter Catheter Tip Pressure Transducer
CLASSIFICATION:	870.1330 Catheter guide wire / DQX 870.2870 Catheter Tip Pressure Transducer /DXO CLASS II
PREDICATE DEVICE:	Verrata PLUS Pressure Guide Wire, K161887

DEVICE DESCRIPTION:

The Verrata PLUS pressure guide wire (hereafter referred to as the "pressure guide wire") is a steerable guide wire with a pressure transducer mounted 3 cm proximal to the tip. The Verrata PLUS guide wire measures pressure when used with the SmartMap, ComboMap, s5 Series, CORE , and IntraSight series of systems. This pressure guide wire will not operate if connected to any other imaging system. The pressure guide wire has a diameter of 0.014" (0.36 mm) and is available in lengths of 185 cm or 300 cm and in straight or pre-shaped tips. The pressure guide wire is packaged attached to the connector with a torque device to facilitate navigation through the vasculature.

INDICATION 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. It can also be used to guide the positioning of a balloon dilatation catheter, as well as other interventional devices. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Attribute/Feature	Comparison of the Predicate Volcano Verrata PLUS Pressure Guide Wire (K161887) and Subject Devices Volcano Verrata PLUS Pressure Guide Wire Alternate Sensor
Indications for Use	SAME
Materials (Guide Wire)	
Tip Coil	SAME
Tip Coil Solder	SAME
Proximal Coil	SAME
Distal Coating	SAME
Sensor Housing	SAME
Pressure Transducer	SAME
	SAME
	SAME
	SAME, except for Silicon Nitride, which is identified in the subject device, but not specified in the predicate device. See table below.
Conductor Wire	SAME
	SAME
Contact Pad	Different, see table below.
Hypotube	SAME
Hypotube Coating	SAME
Core Wire	SAME
Retaining Sleeve	SAME
Conductive Bands	SAME
Insulator Sleeve	SAME
Locking Core	SAME
Insulator Sleeve, conductive band	SAME
Adhesive, UV Cured	SAME
Adhesive, UV Cured	SAME

Attribute/Feature	Comparison of the Predicate Volcano Verrata PLUS Pressure Guide Wire (K161887) and Subject Devices Volcano Verrata PLUS Pressure Guide Wire Alternate Sensor
Adhesive, UV Cured	SAME
Materials (Connector)	
Connector Shell	SAME
Contact	SAME
Locking Clip	SAME
Torsional Spring	SAME
Cable	SAME
	SAME
	SAME
Cable 10 pin connector assembly	SAME
	SAME
	SAME
Materials (Torque Device)	
Body	SAME
Cap	SAME
Collet	SAME
Design	
Core Design	SAME
Tip Design	SAME
Tip Joint Design	SAME
Transducer Location	SAME
Tip Coil to Core Wire	SAME
Core Wire to Housing	SAME
Proximal Locking Core tensile strength	SAME
Turns to Failure	SAME
Connector Cable Routing	SAME
Sensor	
Sensor	Different sensor but same performance specifications
Accuracy	SAME
Drift	SAME
Operating Range	SAME
Dimensions	
Overall Outer Diameter	SAME
Working Length (Distal tip of the wire to the distal end of the connector)	SAME
Radiopaque Tip Coil	SAME

Attribute/Feature	Comparison of the Predicate Volcano Verrata PLUS Pressure Guide Wire (K161887) and Subject Devices Volcano Verrata PLUS Pressure Guide Wire Alternate Sensor
Length	
Sensor Housing Length	SAME
Core Wire Diameter	SAME
Flexible Distal Section	SAME
Packaging Materials	
Carton	SAME
Spiral Dispenser with Clips	SAME
Wire Tray	SAME
Pouch	SAME
RJ50 Cap	SAME
Sterilization and Shelf Life	
Sterilization Method	SAME
Sterilization Assurance Level (SAL)	SAME
Shelf Life	SAME

The following table describes the differences between the two sensors:

Sensor Part	Predicate Volcano Verrata PLUS Pressure Guide Wire (K161887) Sensor Material	Subject Volcano Verrata PLUS Pressure Guide Wire Alternate Sensor	Rationale
Bond Pads (Metallization) (Not blood Contacting)	Base: Tantalum Top Layer: Platinum	Base: Niobium – Titanium-Tungsten Top Layer: Gold	Sensor Manufacturer driven. Alternate Supplier does not have capability to metalize platinum. Gold Pads are beneficial for the Trifilar to Sensor Bond (Compatible with gold plated trifilar)
Base (Handle Layer) (Blood Contacting)	Silicon	Silicon	No Change
Device Layer and	Silicon	Silicon	No Change

Diaphragm (Blood Contacting)	Silicon Oxide (silicon naturally oxidizes when exposed to air)	Silicon Oxide	Passivation layer 1 (adherence, 2nd protection)
		Silicon Nitride	Passivation Layer 2 (Protective). Silicon Nitride is widely used in semi conductor industry for its insulation properties. Biocompatibility studies were executed to verify material impact. All biocompatibility requirements were effectively met per ISO10993. There were no new biological hazards or risks identified compared to predicate device.
Adhesive Marker (Distal Marker aka Dielectric marker) (Blood Contacting)	NA	Silicon Dioxide	Dielectric material added For manufacturing Purposes (Indicator for maximum amount of adhesive and positioning of die in protective housing, yield improvement, cosmetic feature)
Trifilar Insulator (Blood Contacting)	NA	Silicon Dioxide	Dielectric material added for manufacturing purposes (to avoid the Trifilar to short with the Handle Layer, yield improvement).
Electrical Circuit (inside) (Not blood Contacting)	Unknown	Traces of Boron and Phosphorous (< 0.1%)	Not Blood Contacting.

PERFORMANCE DATA:

Performance testing completed for a determination of substantial equivalence included the following:

- EMC and Electrical Safety Testing
- Design Verification
- Self Life Studies
- Drift Performance Testing
- System Verification

CONCLUSION:

All device acceptance criteria were met. Results of testing show that the proposed Verrata PLUS Pressure Guide Wire with alternate sensor meets its intended use. The differences between the subject device and predicate device do not raise new questions of safety and/or effectiveness. Therefore, the proposed Verrata PLUS Pressure Guide Wire with alternate sensor is substantially equivalent to the predicate Verrata PLUS Pressure Guide Wire.