September 28, 2020

Volcano Corporation
Patrick Juarez
Regulatory Specialist
3721 Valley Centre Drive, Ste 500
San Diego, California 92130

Re: K202543
Trade/Device Name: OmniWire Pressure Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DXO
Dated: September 1, 2020
Received: September 2, 2020

Dear Patrick Juarez:

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
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202543

Device Name
OmniWire Pressure Guide Wire

Indications for Use *(Describe)*

The OmniWire 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 facilitate the placement of catheters as well as other interventional devices in coronary and peripheral vessels. 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

OmniWire Pressure Guide Wire Non-Confidential 510(k) Summary

510(k) Number:	K202543
Date Prepared:	September 22, 2020
Owner/Submitter Name & Address:	Volcano Corporation 3721 Valley Center Drive Suite 500 San Diego, CA 92130
Contact Person:	Patrick Juarez Regulatory Affairs Specialist Telephone: (858) 692-3412 E-mail: patrick.juarez@philips.com
Alternative Contact Person:	Donald Ellis Director Regulatory Affairs Telephone: (858) 209-3574 E-mail: donald.ellis@philips.com
Proprietary Name:	OmniWire Pressure Guide Wire
Common/Usual Name:	Pressure Guide Wire
Product Classification Code:	DQX DXO
Product Regulation Number and Name:	870.1330 Wire, Guide, Catheter 870.2870 Catheter Tip Pressure Transducer
Device Class:	II
Predicate Device:	OmniWire Pressure Guide Wire (K192886)
Device Description:	The OmniWire pressure guide wire is a steerable guide wire with a pressure sensor mounted 3 cm proximal to the tip. The pressure guide wire measures pressure when used with the IntraSight and CORE Series of systems and is intended to be used in adult patients eligible for endovascular procedures. The pressure guide wire has a diameter of 0.014" (0.36 mm), a length of 185 cm and is available in straight or pre-shaped tips. It is coated with hydrophilic coating (39 cm length) on the distal portion to reduce surface friction and enhance lubricity. It is also coated with a hydrophobic coating (146 cm length) on the proximal portion to reduce surface friction. The pressure guide wire is packaged attached to the connector with an OmniWire-specific torque device to facilitate navigation through the vasculature.
Indications for Use:	The OmniWire 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 facilitate the placement of catheters as well as other interventional devices in coronary and peripheral vessels. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.
Comparison of Subject to Predicate Device:	The subject device and the predicate device have identical design, materials, physical properties, and performance specifications. Both the predicate and subject device are .014'' (0.36 mm) diameter pressure guide wires. They are both 185 cm in length, use the same pressure sensor, and both utilize a torque device to aid with navigation through vasculature. There are no differences in technological characteristics between the devices. The indications for use, and technological characteristics of the OmniWire Pressure Guide Wire device that are subject to this Special 510(k) submission are the same as the predicate, and are summarized in the following table:

OmniWire Non-Confidential 510(k) Summary

Description	Subject Device	Predicate Device
Proprietary Name	OmniWire Pressure Guide Wire	OmniWire Pressure Guide Wire
Common Name	Pressure Guide Wire	Pressure Guide Wire
Product Classification Code	DQX DXO	DQX DXO
Product Regulation: Number & Name	870.1330, Catheter guide wire and 870.2870, Catheter tip pressure transducer	870.1330, Catheter guide wire and 870.2870, Catheter tip pressure transducer
Device Class	II	II
Device Description	The OmniWire Pressure Guide Wire is a steerable guide wire with a pressure sensor mounted 3 cm proximal to the tip. The pressure guide wire measures pressure when used with the IntraSight and Core Series of systems and is intended to be used in adult patients eligible for endovascular procedures. The pressure guide wire has a diameter of 0.014" (0.36 mm), a length of 185 cm and is available in straight or pre-shaped tips.	The OmniWire Pressure Guide Wire is a steerable guide wire with a pressure sensor mounted 3 cm proximal to the tip. The pressure guide wire measures pressure when used with the IntraSight and SmartMap systems and is intended to be used in adult patients eligible for endovascular procedures. The pressure guide wire has a diameter of 0.014" (0.36 mm), a length of 185 cm and is available in straight or pre-shaped tips.
Indications For Use	The OmniWire 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 facilitate the placement of catheters as well as other interventional devices in coronary and peripheral vessels. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.	The OmniWire 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 facilitate the placement of catheters as well as other interventional devices in coronary and peripheral vessels. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.
Contraindications	The OmniWire pressure guide wire is not intended for use with atherectomy devices or for crossing a total vessel occlusion.	The Verrata PLUS pressure guide wire is not intended for use with atherectomy devices or for crossing a total vessel occlusion.
Compatibility with Systems	Compatible with the IntraSight and CORE Series of systems.	Compatible with the IntraSight and SmartMap systems.
Shelf Life Duration	3 years	2 years

	Technical Specifications	Wire Diameter: 0.0145 Wire Length: 185 cm Sterility Assurance Level (SAL): 10^{-6}	Wire Diameter: 0.0145 Wire Length: 185 cm Sterility Assurance Level (SAL): 10-6
Summary of Non-Clinical Testing:	Bench testing was completed as part of design verification to demonstrate safety and effectiveness, and that the subject device performed as intended. Tests were conducted to evaluate the following: • System Design Verification • Electrical Safety • Electromagnetic Compatibility • Aging Studies		
Summary of Clinical Testing:	No new clinical testing was completed, nor relied upon, in support of this Special 510(k) submission.		
Statement of Equivalence:	The OmniWire Guide Wire device described in this Special 510(k) submission is substantially equivalent to the currently marketed predicate device, K192886, based on comparisons of the device classifications, technological characteristics, and indications for use. The subject device met the pre-determined requirements, and raised no new safety or effectiveness concerns.		