May 5, 2023

Vascular Solutions
Vite Beka
Regulatory Manager
6464 Sycamore Court North
Maple Grove, Minnesota 55369

Re: K230637
Trade/Device Name: Wattson Temporary Pacing Guidewire (2250)
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, LDF
Dated: March 7, 2023
Received: March 7, 2023

Dear Vite Beka:

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,

for Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2023.05.05 19:34:49 -04'00'

Hetal Odobasic
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230637

Device Name

Wattson temporary pacing guidewire (2250)

Indications for Use *(Describe)*

The Wattson temporary pacing guidewire is intended to introduce and position catheters and other interventional devices within the chambers of the heart, including those used within transcatheter aortic valve replacement (TAVR) procedures and balloon aortic valvuloplasty (BAV), while transmitting an electrical signal from an external pulse generator to the heart. The temporary pacing guidewire is not intended to remain in place following the clinical procedure.

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.

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: May 5, 2023

510(k) Number: K230637

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions LLC
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Beka Vite
Regulatory Manager
Tel: 612.441.0914 (direct)

General Information

Trade Name	Wattson™ temporary pacing guidewire
Common / Usual Name	Catheter Guidewire
Classification Name	21 CFR 870.1330, Catheter Guidewire, DQX, Class II Secondary Product Code: LDF
Predicate Device	K192454, Wattson temporary pacing guidewire (Vascular Solutions LLC)

Device Description

The Wattson temporary pacing guidewire is a dual-purpose 0.035" guidewire designed for the delivery of devices and for temporary pacing of the heart. The distal end of the device has an atraumatic pigtail shape. The shaft of the device has a hydrophilic coating.

Pacing is achieved through a bipolar electrode configuration integrated in the shaft of the guidewire. The electrodes terminate in a single positive electrode at the distal tip of the device and three discrete negative electrodes located proximal to the tip within the pigtail section. The entire device is visible using standard fluoroscopic methods.

The device is packaged with a proprietary adapter that locks on to the proximal end of the guidewire and converts it to discrete positive and negative terminal pins. The terminal pins of the adapter are compatible with standard external pulse generators. Unshrouded adaptor pins are provided to ensure compatibility with all connecter cable terminals.

The Wattson temporary pacing guidewire is sterilized with ethylene oxide.

Indications for Use

The Wattson temporary pacing guidewire is intended to introduce and position catheters and other interventional devices within the chambers of the heart, including those used within transcatheter aortic valve replacement (TAVR) procedures and balloon aortic valvuloplasty (BAV), while transmitting an electrical signal from an external pulse generator to the heart. The temporary pacing guidewire is not intended to remain in place following the clinical procedure.

Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics between the Wattson temporary pacing guidewire and the predicate device are provided in the following table.

Comparison of Technological Characteristics		
Characteristic	**Subject Device**	**Primary Predicate Device**
	Wattson temporary pacing guidewire	**Wattson temporary pacing guidewire**
Indications for Use	The Wattson™ temporary pacing guidewire is intended to introduce and position catheters and other interventional devices within the chambers of the heart, including those used within transcatheter aortic valve replacement (TAVR) procedures and balloon aortic valvuloplasty (BAV), while transmitting an electrical signal from an external pulse generator to the heart. The temporary pacing guidewire is not intended to remain in place following the clinical procedure.	The Wattson™ temporary pacing guidewire is intended to introduce and position catheters and other interventional devices within the chambers of the heart, including those used within transcatheter aortic valve replacement (TAVR) procedures and balloon aortic valvuloplasty (BAV), while transmitting an electrical signal from an external pulse generator to the heart. The temporary pacing guidewire is not intended to remain in place following the clinical procedure.
Contraindication	The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.	The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.
Anatomical sites	Left Ventricle	Left Ventricle
Materials of construction	Stainless Steel Wire with fluoropolymer outer jacket (FEP) and stainless-steel electrodes	Stainless Steel Wire with Polyetheretherketone outer jacket (PEEK) and stainless-steel electrodes
Length	280 cm	280 cm
Wire OD	0.035”/0.89 mm	0.035”/0.89 mm
Method of Sterilization	Ethylene Oxide	Ethylene Oxide
Single Use or Reusable	Single Use	Single Use
Coating	Silicone Oil Lubricant	Hydrophilic coating
Radiopacity	Yes	Yes

Comparison of Technological Characteristics		
Characteristic	**Subject Device**	**Primary Predicate Device**
	Wattson temporary pacing guidewire	**Wattson temporary pacing guidewire**
Tip Configuration	Pigtail	Pigtail
External Pacemaker Connections	Removable guidewire adapter terminating in two shrouded positive/negative connectors	Removable guidewire adapter terminating in two shrouded positive/negative connectors and two unshrouded adapter pins
Pulse Generator compatibility	Compatible with standard external pulse generators	Compatible with standard external pulse generators

Performance Data

Biocompatibility

The biocompatibility evaluation for the Wattson temporary pacing guidewire was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Wattson temporary pacing guidewire is considered an externally communicating device in contact with circulating blood and tissue for a limited period of time (<24 hours) during use. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

Performance Data - Bench

The device design was verified through performance, patient safety, structural integrity, infection, microbial and particulate contamination, and device interface tests.

Performance Data – Animal:

A Good Laboratory Practice (GLP) Safety study was performed to demonstrate the substantial equivalence of the Wattson temporary pacing guidewire in comparison to the predicate Wattson temporary pacing guidewire in a porcine model. The testing was performed in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies. The subject Wattson temporary pacing guidewire shares the same fundamental scientific technology as the predicate device.

The GLP Safety study demonstrated that the Wattson temporary pacing guidewire performed similarly to the predicate with regard to adverse events and other animal health concerns. No animals

experienced sustained arrhythmia in the post-rapid pacing monitoring period, all animals returned to normal sinus rhythm after rapid pacing was turned off, and there were no histological findings that indicate any differences between the subject device and its predicate.

Conclusion

Results of biocompatibility, benchtop, and animal studies performed on the Wattson temporary pacing guidewire did not raise any new questions of safety or effectiveness compared to the predicate device. The Wattson temporary pacing guidewire is substantially equivalent to the predicate device.