January 15, 2020

Vascular Solutions
Nancy Frame
Sr. Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K192454
Trade/Device Name: Wattson Temporary Pacing Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 18, 2019
Received: December 20, 2019

Dear Nancy Frame:

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,

Hetal Patel
Assistant Director
Implantable Electrophysiology Devices Team
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)*
K192454

Device Name
Wattson™ temporary pacing guidewire

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.

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510(k) Summary

[As required by 21 CFR 807.92]

510(k) NUMBER: K192454

SUBMITTER

Vascular Solutions

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Minneapolis, MN 55369 USA

Establishment Registration # 2134812

Phone: 763.656.4230 (direct)

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Contact Person: Nancy Frame, Sr. Regulatory Product Specialist

Date Prepared: September 5, 2019

DEVICE

Name of Device: Wattson™ temporary pacing guidewire

Common or Usual Name: Catheter Guidewire

Classification Name: Catheter Guidewire (21 CFR 870.1330)

Regulatory Class: II

Primary Product Code: DQX

Secondary Product Code: LDF

PREDICATE DEVICES

Primary Predicate:

Manufacturer: Medtronic

Device Name: Confida™ /Breaker Guidewire

510(k) No: K181001 (cleared May 3, 2018), Class II, Product Code DQX; classified per 21 CFR 870.1330

Secondary Predicate:

Manufacturer: Bard

Device Name: Bard® Temporary Pacing Electrode Catheter

510(k) No: K800298 (cleared April 16, 1980), Class II, Product Code LDF; classified per 21 CFR 870.3680

DEVICE DESCRIPTION

The Wattson temporary pacing guidewire is a dual-purpose 0.035" guidewire designed for the delivery of devices and for temporary rapid pacing of the heart. The distal end of the device has an atraumatic pigtail shape. The shaft of the device has a silicone lubricant applied to the outer surface.

Rapid 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.

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 DEVICES

This submission is seeking the clearance of the Wattson temporary pacing guidewire which has similar uses, fundamental technologies, principals of operation and performance as the identified predicate devices. The Wattson temporary pacing guidewire is similar to the Confida Brecker wire in that it is used to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart. It is similar to the Bard Temporary Pacing catheter in that it is used to transmit an electrical signal from an external pulse generator to the heart. Where there are technological differences, results of bench and animal tests confirm that the Wattson temporary pacing guidewire is substantially equivalent to the predicate devices. A comparison of the technological characteristics for the Wattson temporary pacing guidewire against the predicate devices is as follows:

Substantial Equivalence Comparison

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Wattson temporary pacing guidewire	**Confida Guidewire**	**Temporary Pacing Electrode Catheter**
510(k)	K19XXXX	K181001	K800298
Manufacturer	Vascular Solutions	Medtronic	Bard
Product Class	II	II	II
Product Classification	870.1330	870.1330	870.3680
Product Code	DQX; LDF	DQX	LDF
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 Medtronic Confida™ Brecker guidewire is intended for use to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart, including transcatheter aortic valve replacement (TAVR).	Bard® Temporary Pacing Catheters are designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device. When an internal lumen is present (other than the one used for balloon inflation), it may be used for fluid infusion, pressure monitoring, or blood sampling.
Contraindication	The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.	The Medtronic Confida™ Brecker Guidewire is contraindicated for patients presenting with an intolerance to anticoagulation therapy and	None

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Wattson temporary pacing guidewire	**Confida Guidewire**	**Temporary Pacing Electrode Catheter**
		unheparinized patients. The guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.	
Anatomical sites	Left Ventricle	Left Ventricle	Right Ventricle
Materials of construction	Stainless Steel Wire with fluoropolymer jacket and stainless-steel electrodes	Stainless Steel wire with fluoropolymer coating.	Woven or extruded polyurethane jacketed shaft with platinum or stainless-steel electrodes
Length	280 cm	260 cm	100, 110, 115, 125 cm
Wire OD	0.035”/0.89 mm	0.035”/0.89 mm	N/A
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Single Use or Reusable	Single Use	Single Use	Single Use
Coating	Fluropolymer outer Jacket (FEP) with Silicone Oil Lubricant.	Fluoropolymer (PTFE) coating	Polyurethane Outer Jacket
Radiopacity	Yes	Yes	Yes
Tip Configuration	Pigtail	Preformed 360° curved tip (pigtail)	Straight, Preshaped angle tip
External Pacemaker Connections	Removable guidewire adapter terminating in two shrouded positive/negative connectors	N/A	Two incorporated shrouded positive/negative connectors.
Pulse Generator compatibility	Compatible with standard external pulse generators	N/A	Compatible with standard external pulse generators

PERFORMANCE DATA

Biocompatibility Testing

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
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

Performance Testing- Bench

The device design was verified through the following tests:

- Dimensional Verification
- Visual Inspection
- Tensile Strength
- Track Force
- Guidewire Support Profile
- Distal Flex Force
- Shaft Friction Force
- Electrode Size
- Electrode Location
- Device Continuity
- Particulate Evaluation
- Corrosion Resistance
- Radiopacity

Performance Data – Animal:

Animal testing was performed to demonstrate the substantial equivalence of the Wattson temporary pacing guidewire to the predicates Confida Breaker Guidewire and Bard Temporary Pacing Catheter 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 devices.

A GLP study demonstrated that the Wattson temporary pacing guidewire and the predicate (control) devices performed similarly 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 test and control group.

A second GLP study successfully demonstrated that the Wattson temporary pacing guidewire and the predicate (control) devices are similar in performance and handling during simulated clinical use in the swine model. In all cases: the Wattson wire provided a clinically significant reduction in blood pressure to adequately allow for successful BAV inflation; and the interventionalist was able to properly position the device, successfully deliver the BAV device and successfully connect to the external pacing programmer. Animals were monitored for 30 minutes post-procedure and demonstrated a return to normal sinus rhythm and were free of any concerning cardiac events.

Performance Testing – Clinical:

Twenty subjects underwent TAVR procedures and were treated with the Wattson temporary pacing guidewire in a single-center, pre-market, prospective study.

The Wattson temporary pacing guidewire offered predictable guidewire support with concomitant reliable bipolar pacing at low thresholds to allow safe transcatheter heart valve delivery in the treated cohort. In this experience the Wattson wire performance indicates the device has the potential to make TAVR a more efficient procedure in patients.

CONCLUSIONS

The results of bench and animal tests confirm that the Wattson temporary pacing guidewire, subject of this 510(k), is substantially equivalent to the predicate devices. The Wattson temporary pacing guidewire is similar to the predicate devices in its indications for use and substantially equivalent in technology, materials, and performance to the predicates. Performance data demonstrates that the Wattson temporary pacing guidewire performs as well as the Confida Breaker Guidewire and Bard Temporary Pacing Catheter. Therefore, it can be concluded that the Wattson temporary pacing guidewire is substantially equivalent to the predicate devices.