DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 8, 2016

Argon Medical Devices, Inc.
Beckie Ellis
Vice President, Regulatory Affairs/Quality Assurance
1445 Flat Creek Road
Athens, Texas 75751

Re: K160785
Trade/Device Name: WORKER Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 3, 2016
Received: November 7, 2016

Dear Ms. Ellis:

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 yours,

Brian D. Pullin -S

for 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)*
K160785

Device Name
WORKER™ Guidewire

Indications for Use *(Describe)*
WORKER™ Guidewires are for use in facilitating the placement of catheters within the coronary and peripheral vasculature.

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.

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510(k) Summary

Date Prepared: October 10, 2016

Company: Argon Medical Devices, Inc.
1445 Flat Creek Road Athens,
Texas 75751
Facility Registration number: 1625425

Contact: Suzanne Cheang
Regulatory Affairs Manager
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Email: suzanne.cheang@argonmedical.com

Device trade name: WORKER™ Guidewire

Device Common Name: Guidewire

Device classification: Catheter guide wire
Product code, DQX
21 CFR 870.1330
Class II

Legally marketed device to which the device is substantially equivalent: K082094 Bard PTFE Coated Guidewires

Description of the device: WORKER™ Guidewires have a fixed stainless steel core with polytetrafluoroethylene (PTFE) coated stainless steel spring wire to reduce friction. The WORKER™ Guidewires have a diameter of either 0.035" or 0.038" and range in length from 80 to 260 cm. Guidewires are marketed in Standard, Amplatz and Bentson iterations.

Indications for Use: WORKER™ Guidewires are for use in facilitating the placement of catheters within the coronary and peripheral vasculature.

Technological Characteristics: Comparisons of the WORKER™ Guidewire and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

The WORKER™ Guidewire is similar in design – device dimensional specifications, intended use, shelf life, materials and sterilization process of that of the predicate devices. Below is the summarized technological characteristics comparison:

Feature	WORKER™ Guidewire	Bard PTFE (Teflon®) Coated Guidewires
Indication for Use	WORKER™Guidewires are for use in facilitating the placement of catheters within the coronary and peripheral vasculature.	Bard PTFE Coated Guide Wires are indicated for percutaneous entry of a guiding catheter into a vessel using standard percutaneous methods (Seldinger's Technique)
Sizes	0.035" & 0.038"	0.035" & 0.038"
Tip Styles	J & Straight	J & Straight
Materials	Stainless steel, PTFE	Stainless steel, PTFE
Disposable	Yes	Yes

Performance tests (Non-Clinical):

No performance standards have been established under section 514, performance standards, of the Food, Drug and Cosmetic Act for these devices. A series of testing was conducted in accordance with protocols based on requirements outlined in guidance's and industry standards and the below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

Where appropriate, the tests were based on the requirements of the following documents:

- FDA guidance Coronary and Cerebrovascular Guidewire Guidance January 1995.
- ISO 11135-1Sterilization of heath care products- Ethylene Oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process.

The WORKER™ Guidewire is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and Indications for Use. The device design has been qualified through the following tests:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adherence/Integrity
- Catheter Compatibility
- Particulate Testing
- Radiopacity

Biocompatibility testing per ISO 10993-1 was performed, consisting of the following tests:

- Cytotoxicity
- Sensitization
- Acute systemic toxicity
- Hemocompatibility
- Irritation/intracutaneous reactivity

The results of this testing demonstrates that the WORKER™ Guidewire, is substantially equivalent to the predicate devices and did not raise new safety or performance questions.

Substantial Equivalence:

Based on the Indication for Use, design safety and performance testing, the subject WORKER™ Guidewire meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate devices.