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

August 18, 2016

Concert Medical, LLC
% Pamela Papineau
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Ave
Ayer, Massachusetts 01432

Re: K153397
Trade/Device Name: S-Wire Guidewire System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 17, 2015
Received: November 24, 2015

Dear Ms. Papineau:

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,

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)*
K153397

Device Name
S-Wire Guidewire System

Indications for Use *(Describe)*
The S-Wire Guidewire System is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used in trans-catheter aortic valve implantation (TAVI) procedures.

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."

510(k) Summary – Revised (Clean Copy)

Date Prepared: **15 July 2016**

General Information

Owner's Name: Concert Medical, LLC
Address: 77 Accord Park Drive
Norwell, MA 02061
Telephone: 781-871-7882
Fax: 781-724-4555

Contact Person: Pamela Papineau, RAC (US, EU, CAN)
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432
Telephone: (978) 772-3552
Fax: (978) 796-5460

Subject Device:

Trade Name: S-Wire Guidewire System
Common Name: Catheter Guide Wire
Product Code: DQX
FDA Regulation: 21 CFR 870.1330 – Catheter Guide Wire
Device Classification: Class II

Predicate Device:

Product Name: Lake Region Pre-Formed Guidewire (Boston Scientific Safari Pre-Shaped TAVI Guidewire)
Common Name: Catheter Guide Wire
Product Code: DQX
FDA Regulation: 21 CFR 870.1330 – Catheter Guide Wire
Device Classification: Class II
Premarket Notification: K130798, K151244

Indications for Use

The S-Wire Guidewire System is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used in trans-catheter aortic valve implantation (TAVI) procedures

Device Description:

The S-Wire Guidewire System is a sterile, single-use guidewire used for the placement of interventional devices within the aorta and the chambers of the heart. The S-Wire has a 0.035" diameter, and an overall length of 260 cm. The S-Wire construction consists of a nickel-titanium alloy core wire that is PTFE coated, ground and thermally formed. The S-Wire distal coil is

made of 304V stainless steel; the distal and proximal ends of the stainless steel coil is bonded to the core wire. The distal portion of the S-Wire has silicone coating. The distal end of the S-Wire has a pre-formed double curve shape consisting of an approximately 360º bend with an outer diameter of approximately 3 cm, and a small S-curve at the distal tip of the wire that is fully contained within the 3 cm curved area. The S-Wire Guidewire System includes a disposable plastic 9 Fr introducer (6 inches long) that is used as an aid in loading the S-Wire into an intravascular catheter.

Substantial Equivalence

The Concert Medical S-Wire Guidewire System is substantially equivalent to the Lake Region Pre-Formed Guidewire (K151244 & K130798), which is marketed by Boston Scientific Corp. as the Safari Pre-Shaped TAVI guidewire. Substantial equivalence, which is summarized below, is based on indications for use, physical and technological characteristics, and comparative device testing.

	Concert Medical S-Wire Guidewire System (current submission)	Lake Region Pre-Formed Guidewire (K151244 & K130798)
Device Common/Usual Name	Catheter Guide Wire	Catheter Guide Wire
Device Class	Class II	Class II
Product Code / Regulation	DQX / 21 CFR 870.1300	DQX / 21 CFR 870.1300
Regulation Name	Catheter Guide Wire	Catheter Guide Wire
Prescription Use	Rx Only	Rx Only
Indications for Use	To facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used in trans-catheter aortic valve implantation (TAVI) procedures	To facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used within trans-catheter aortic valve procedures
Guidewire OD	0.035”	0.035”
Guidewire Length	260 cm	260 cm – 300 cm
Guidewire Materials	Nickel-titanium superelastic alloy, 304V stainless steel, adhesive	A313 stainless steel
Guidewire Coating	PTFE (shaft); Silicone (distal coil)	PTFE
Tip Shape	Atraumatic double curve	Atraumatic double curve
Sterile Device?	Yes	Yes
Sterilization Type	Ethylene Oxide	Ethylene Oxide
EO Sterilization Residuals	Per ISO 10993-7	Per ISO 10993-7
Disposable / Reusable	Disposable	Disposable

Performance Testing:

Performance testing for the Concert Medical S-Wire Guidewire System consists of the measurement of physical characteristics and device integrity in accordance with FDA’s *Coronary and Cerebrovascular Guidewire Guidance* and ISO 11070 (*Sterile, single-use intravascular catheter introducers*); testing included dimensional inspection, tensile strength (guidewire and introducer), distal loop compression force, distal tip shape retention, tip stiffness, shaft stiffness, coating integrity, particulate evaluation, catheter compatibility, guidewire flex testing, guidewire fracture testing and corrosion resistance. Where applicable, comparative test results are provided

for the S-Wire and the predicate device. Additional testing included in this Premarket Notification includes ISO 10993 biocompatibility testing (cytotoxicity, irritation, sensitization, acute systemic toxicity, hemocompatibility and pyrogen) and sterile package integrity testing (pouch seal tensile strength, burst strength and dye penetration). The Concert Medical S-Wire Guidewire System met all predetermined acceptance criteria and compared favorably with the predicate device.

Conclusion:
The Concert Medical S-Wire Guidewire System has been demonstrated to be substantially equivalent to the predicate device.