



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

June 11, 2015

Lake Region Medical
Mathew Pexa
Sr. Regulatory Specialist
340 Lake Hazeltine Dr.
Chaska, Minnesota 55318

Re: K151244
Trade/Device Name: Pre-Formed Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 8, 2015
Received: May 11, 2015

Dear Mr. Pexa:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



PRODUCT: PREFORMED GUIDEWIRE SPECIAL 510(K)
SUBMISSION DATE: May 8, 2015
SUBMISSION TYPE: SPECIAL 510(k)

510(k) SUMMARY

May 8, 2015

This summary is being included in the submission in lieu of a statement of availability.

2.1 MANUFACTURER / REGISTRATION INFORMATION

Lake Region Medical	<i>Telephone:</i>	952-448-5111
340 Lake Hazeltine Dr.	<i>Fax:</i>	952-448-3441
Chaska, Mn 55318	<i>Contact Person:</i>	Mathew Pexa
<i>FDA REGISTRATION NUMBER: 2126666</i>	<i>Title:</i>	Sr. Regulatory Specialist

2.2 DEVICE TRADE NAME / PROPRIETARY NAME

Pre-Formed Guidewires

2.3 DEVICE COMMON NAMES / USUAL NAMES / CLASSIFICATION NAMES

CATHETER GUIDEWIRE (DQX)

2.4 CLASS OF DEVICE

These devices are commonly known as guides, guidewires, or spring guidewires. The current classification name and product code is Catheter Guidewire (DQX) and is considered a Class II device per 21 CFR Part 870.1330.

2.5 IDENTIFICATION OF PREDICATE DEVICE(s)

K130798 Pre-Formed Guidewires (Lake Region Medical)

2.6 DEVICE DESCRIPTION

The 0.035" diameter, 260-300cm length guidewire is composed of two primary wire components: a core and a coil. Both components are manufactured from Stainless Steel per ASTM A313. The core wire is a stainless steel wire which forms the inner body of the guidewire. The coil component is the guidewire's outer layer and is a stainless steel wire coated in Green Polytetrafluoroethylene (PTFE). The coil and the core components are welded together on the distal and proximal ends, forming the guidewire. The distal ends are shaped into a double-curve. The following table shows the characteristics of the product family:

Outside Diameter:	0.035"
Overall Length:	260cm to 300cm
Tip Shape:	Double-Curve
Tip Sizes:	Extra Small - Large

2.7 COMPLIANCE WITH APPLICABLE STANDARDS

LRM has determined that no mandatory standards, performance standards, or special controls have been established for these devices under Section 514 of the Medical Device Amendments to Federal Food, Drug, and Cosmetic or by any subsequent regulatory action. However, the following standards are referenced within this filing: ISO 10993, ISO 11070, ISO 11135, ISO 11138.

2.8 INTENDED USE STATEMENT

Pre-Formed Guidewires are intended to facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used within transcatheter aortic valve procedures.

NOTE: This modification does not alter its intended use.

2.9 CONTRAINDICATIONS

This wire is not intended for use in the cerebrovasculature or coronary arteries.



PRODUCT: PREFORMED GUIDEWIRE SPECIAL 510(K)

SUBMISSION DATE: May 8, 2015

SUBMISSION TYPE: SPECIAL 510(k)

2.10 TECHNOLOGICAL CHARACTERISTICS

The design specifications are substantially equivalent to the existing Pre-Formed Guidewires

2.11 QUALITY SYSTEM CONTROL

DESIGN CONTROLS

LRM is in conformance with the design control procedure requirements as specified in 21 CFR Part 820.30. Risk analysis was completed by means of a Failure Mode and Effects Analysis and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria were met.

MATERIALS / SUPPLIER / PRODUCT / PROCESS CONTROLS

LRM has formal quality systems in place to assure that each product manufactured remains equivalent to the predicate products, and that the changes will not have an adverse effect on safety or effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Supplier Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size / group.

2.12 QUALIFICATION TESTING

The conclusions drawn from bench testing and biocompatibility testing demonstrate compliance with the design input summary which shows the device is at least as safe and effective as the current legally marketed device.

BENCH TESTING

In order to demonstrate equivalence of the guidewire, Lake Region Medical performed bench testing to establish requirements. Test devices were manufactured and inspected according to established requirements for visual/tactile, dimensional and mechanical attributes. The devices were then subjected to the following test methods to show the devices comply with the design input summary:

- | | |
|------------------------------|----------------------------|
| - Dimensional | - ISO Visual |
| - FDA Tensile Strength | - ISO Fracture |
| - FDA Tip Flexibility | - ISO Flex |
| - FDA Catheter Compatibility | - ISO Corrosion Resistance |
| - Packaging Study | - Linear Stiffness |
| - Tip Shape Retention | |
| - Particulate | |

BIOCOMPATIBILITY TESTING

There were no changes to materials used in the design or manufacture of the Pre-Formed guidewire family; therefore, no additional biocompatibility tests were completed.

ANIMAL STUDY

A GLP Animal study was completed to evaluate safety and performance of the guidewire compared to the currently marketed device. The study shows the guidewires are substantially equivalent to the legally marketed device.

2.13 CHANGES FROM PREDICATE DEVICE

- Additional tip shape, Extra Small
- Distal core grind diameter minimum made larger

2.14 SUBSTANTIAL EQUIVALENCE DATA

The changes included in this 510(k) for the Pre-Formed guidewire family do not change the indications for use of the Mandrel guidewires and is not a change to the fundamental scientific technology. The information summarized above shows the device will perform as well as the previously marketed device.