MAY 2 0 2014

5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Y-Wire 2 device is provided below.

Device Common Name: Orthopedic Wire Passer

Device Proprietary Name: Y-Wire 2

Submitter: Wyatt Geist - CEO
Safewire, LLC
8963 Stirling Rd Suite 7
Cooper City, FLA 33328

Contact: Stephen Inglese
Consultant to Safewire, LLC
Quality Solutions and Support, LLC
Phone: 561-251-0876
Email: swiqss1@gmail.com

Date Prepared: 05/14/2014

Classification
Regulation: 21 CFR 888.4540 - Orthopedic manual surgical instrument

Panel: Orthopedics

Product Code: **HXI**

Legally Marketed Predicates - K2M – K Wire and Nuvasive – K Wire

Indication for Use: Y-Wire 2 is intended for use by surgeons to assist with the proper introduction and placements of orthopedic instruments and implants.

Device Description:

The Y-Wire 2 is an orthopedic guidewire with a distinctive distal split tip that is designed to prevent inadvertent advancement of the wire in tissue. Upon exiting a cannula, the distal tips will deploy to stop further advancement past the desired location. By design the distal tip is splayed 30^0 degrees for a distance of 11mm. The guidwire is made of Nitinol. The Y-Wire 2 is manufactured in five (5) diameters: 1.10mm, 1.28mm, 1.40mm, 1.45mm and 1.50mm all have the same length of 560mm.

Performance Data:

1) **Biocompatibility –** FDA Guidance / ISO 10993

Biocompatibility study was accomplished to ensure the interaction between the material of the Y-Wire 2 device and patient body tissues and other related body systems to determine the outcome when the device is in use.

2) **Packaging**

Safewire, LLC utilized an ISO 13485 packaging facility that accomplished the appropriate IQ (Installation Qualification), OQ (Operating Qualification) and PQ (Process Qualification) packaging validations. These processes when successfully completed through protocol development and final report outcomes determined the method in which the Y-Wire 2 is to be packaged.

3) **Performance – Bench Testing**

Static push through force testing demonstrated that the force required to push the Y-wire through a bone test fixture was greater than that for the predicate devices, thus reducing the risk of inadvertent advancement.

Substantial Equivalence:

The Y-Wire 2 is substantially equivalent to the predicate devices based on similar intended use and technological characteristics.

The intended use of the Y-Wire 2 is the same as the predicate device in that it is designed for minimally invasive surgery as a guidewire used by surgeons to assist with proper introduction and placement of surgical instruments and implants.

The technological characteristics are compared in the Device Comparison Table below. The Y-Wire 2 is available in similar diameters and lengths to that of the predicate. The difference in technological characteristics is the design of the tip. The Y-Wire 2 has a "Y" shaped tipped whereas the predicate device tip is straight and pointed. Additionally, the Y-Wire 2 is made of Nitinol whereas the predicate device is made of stainless steel.

Summary of Substantial Equivalence:

The differences in technological characteristics do not raise new types of safety and effectiveness questions. Specifically, the "Y" shaped tip raises the same types of safety questions as a straight tipped guidewire. The material used for the Y-Wire 2 is Nitinol. The Nitinol material is recognized for its superelasticity and shape memory which exceeds that of the predicate devices which are manufactured with Stainless Steel. The Y-Wire 2 device length of 560mm exceeds the length of the predicates to provide the surgeon with the additional wire length to support the surgical procedure. The splayed tip of the Y-Wire 2 is designed to avoid advancement of the guidewire through bone whereas the predicates contain a straight and pointed tip. The Y-Wire 2 is provided sterile versus the predicates which are provided non-sterile. This provides the surgical staff with a device ready for use. The performance data provided in this 510(k) show equivalence to the predicate and therefore the Y-Wire 2 can be found substantially equivalent to the predicate device.

Sterilization Information:

The Y-Wire 2 will be provided sterile with a shelf life of five (5) years. The sterilized method used is E-Beam in accordance with ANSI/AAMI/ ISO 11137-1&2

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

May 20, 2014

Safewire, LLC
% Mr. Stephen W. Inglese
Founder and CEO
Quality Solutions and Support, LLC
520 Butternut Drive #8 PMB #256
Holland, Michigan 49424

Re: K140576
Trade/Device Name: Y-Wire 2
Regulation Number: 21 CFR 888.4540
Regulation Name: Orthopedic manual surgical instrument
Regulatory Class: Class I
Product Code: HXI
Dated: March 25, 2014
Received: March 26, 2014

Dear Mr. Inglese:

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" (21CFR 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,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic 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)*
K140576

Device Name
Y-Wire 2

Indications for Use *(Describe)*
Y-Wire2 guidewire is intended for use by surgeons to assist with the proper introduction and placement of orthopedic instruments and implants.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

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:

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