May 1, 2019

Stryker Neurovascular
Lorraine Mazzeo
Senior Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re:  K190843
   Trade/Device Name:  Synchro² Support Guidewire
   Regulation Number:  21 CFR 870.1330
   Regulation Name:  Catheter Guide Wire
   Regulatory Class:  Class II
   Product Code:  MOF, DQX
   Dated:  March 29, 2019
   Received:  April 1, 2019

Dear Lorraine Mazzeo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng
-S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Synchro² Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Type of Use (Select one or both, as applicable)

- [x] 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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"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

**Device Trade Name:** Synchro² Support Guidewire  

**Common Name:** Wire, Guide, Catheter  

**Classification Name:** Wire, Guide, Catheter, 21CFR 870.1330, Class II  

**Product Code:** MOF, DQX  

**Submitter:** Stryker Neurovascular  
47900 Bayside Parkway  
Fremont, CA 94538  
Facility Registration #300853977  

**Contact:** Lorraine Mazzeo  
Senior Regulatory Affairs Specialist  
Tel 510 – 413-2676  
E-mail: lorraine.mazzeo@stryker.com  

**Date Prepared:** March 29, 2019

<table>
<thead>
<tr>
<th><strong>Primary Predicate Device</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>K053268</strong></td>
<td><em>Synchro² Guidewires</em></td>
<td><em>(clearance granted 13 Mar 2006)</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Reference Predicate Devices</strong></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>K002907</strong></td>
<td><em>Synchro 14 Guidewires</em></td>
<td><em>(clearance granted 03 Mar 2001)</em></td>
<td></td>
</tr>
<tr>
<td><strong>K971254</strong></td>
<td><em>Transend Guidewires</em></td>
<td><em>(clearance granted 01 Jul 1997)</em></td>
<td></td>
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</tbody>
</table>
Device Description

Like the primary predicate device, the Synchro² Support Guidewire is a single-use product with a shapeable tip in straight and pre-shape configurations used to gain intravascular access to and facilitate the positioning and exchange of interventional devices in small diameter, tortuous vasculature for neuro and peripheral diagnostic and interventional procedures. The wire can be torqued to facilitate navigation through the vasculature.

Accessories

The Synchro² Support Guidewire is shipped with a Torque Device, commercially available from Merit Medical (K936032) and a Guidewire Introducer commercially available from B. Braun (K760386).

Indications for Use

The Indications for Use for the Synchro² Support Guidewire are the same as the primary predicate Synchro² Guidewire and are as follows:

The Synchro² Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Technological Characteristics and Product Feature Comparison

The subject device, Synchro² Support Guidewire is substantially equivalent to the primary predicate device in terms of:

- indications for use
- materials and manufacturing processes
- fundamental scientific technology
- fundamental design
- materials and processes for packaging and sterilization of devices

A tabular comparison of the specific technological characteristics between the predicate devices and subject device is provided below.
## Feature

<table>
<thead>
<tr>
<th>Feature</th>
<th>Primary Predicate Device (K053268)</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The Synchro(^2) Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.</td>
<td>Same</td>
</tr>
<tr>
<td>Device Description</td>
<td>The Synchro(^2) Guidewire series is a single-use product with a shapeable tip, used to gain intravascular access to and facilitate the positioning and exchange of interventional devices in small diameter, tortuous vasculature for neuro and peripheral diagnostic and interventional procedures. The wire can be torqued to facilitate navigation through the vasculature.</td>
<td>Same</td>
</tr>
<tr>
<td>Target Population</td>
<td>The Synchro(^2) Guidewire series will be used in patients undergoing endovascular treatment including neurovascular and peripheral vasculatures.</td>
<td>Same</td>
</tr>
<tr>
<td>Anatomical Sites</td>
<td>Peripheral and neuro vasculature</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>21CFR 870.1330</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation Name</td>
<td>Guide Wire</td>
<td>Same</td>
</tr>
<tr>
<td>Regulatory Class</td>
<td>II</td>
<td>Same</td>
</tr>
<tr>
<td>Product Code</td>
<td>DQX</td>
<td>MOF, DQX</td>
</tr>
</tbody>
</table>
### Feature | Primary Predicate Device (K053268) | Subject Device
--- | --- | ---
Core Wire | 304 Stainless Steel, PTFE coated on the proximal section | Same
Core Wire Length | 200cm Access Length 300cm Exchange Length | 215cm Access Length 300cm Exchange Length
Guidewire Tip | Nickel-Titanium, Micro-Machined Nitinol | Same
Radiopaque Coil | Platinum, 10cm | Platinum, 7cm
Adhesive | UV Curable Adhesive | Same
Primer | Parylene Dimer | Same
Hydrophilic Top Coat | Proprietary Hydrophilic Top Coat | Same
Hydrophilic Base Coat | Proprietary Hydrophilic Base Coat | Same
Guidewire Introducer | Available commercially per K760389 | Same
Torque Device | Available commercially per K936032 | Same
Dispenser Hoop | High Density Polyethylene | Same
Accessory Card | Clay Coated Solid Bleached Sulfate (CCSBS) | Same
Sterile Pouch | Tyvek® - Polyethylene | Same
Shipping Carton | Solid Bleached Sulphate (SBS) | Same
Sterilization Method | 100% Ethylene Oxide | Same
How Supplied | Sterile/Single Use | Same
Risk Assessment

Risk assessment of the modifications has been conducted in accordance with EN ISO 14971:2012. The risk documentation was updated to support the modifications, and Stryker Neurovascular has determined that the modifications to the primary predicate device raise no new questions of safety or effectiveness. The modifications did not result in any new failure modes nor were there any changes to existing failure modes. Results of confirmatory testing have demonstrated the subject device is substantially equivalent to the primary predicate device.

Testing Summary

The results of confirmatory testing conducted on the subject device demonstrate that it performs as designed and is suitable for its intended use. Specifically, the following tests were performed on the subject device.

<table>
<thead>
<tr>
<th>Test</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip Stiffness</td>
<td>Met established acceptance criteria</td>
</tr>
<tr>
<td>Fracture</td>
<td>Met established acceptance criteria</td>
</tr>
<tr>
<td>Tip Integrity</td>
<td>Met established acceptance criteria</td>
</tr>
<tr>
<td>Particulate characterization</td>
<td>Met established acceptance criteria</td>
</tr>
<tr>
<td>Coating integrity visual inspection</td>
<td>Met established acceptance criteria</td>
</tr>
</tbody>
</table>

Biocompatibility

Biocompatibility testing was completed for the previously cleared devices under K053268. These results apply to the subject device because it uses the same materials and processes as previously cleared primary predicate device. The results demonstrate that the subject device with its accessories meet biological safety requirements per EN ISO 10993-1:2009 (“Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”) for externally communicating medical devices with circulating blood contact for less than 24 hours. This statement is supported by standards assessment conducted by Stryker.
Sterilization and shelf life

The device and its accessories, are sterilized by 100% Ethylene Oxide and have been adopted into a validated sterilization process in accordance with the principles of EN ISO 11135: 2014/AC: 2014 (“Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices”). This statement is supported by standards assessment conducted by Stryker.

There are no material changes. All components that are changing are metal, which are not affected by aging. There are no changes to existing shelf life.

Summary of Substantial Equivalence

The subject device is substantially equivalent to the primary predicate device with regards to device design, materials, intended use, and patient population. The conclusions drawn from the risk assessments and confirmatory testing conducted demonstrate that the subject device performs as designed, is as safe, as effective, and performs as well as the predicate device.