Stryker Neurovascular
Hailey Hinkle
Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

September 25, 2020

Re: K202522
Trade/Device Name: Synchro SELECT Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: August 31, 2020
Received: September 1, 2020

Dear Hailey Hinkle:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202522

Device Name
Synchro SELECT Guidewire

Indications for Use *(Describe)*
The Synchro SELECT 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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K202522

510(k) Summary

Submitter Name, Address and Content:

Submitter: Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515
(FDA Registration Number: 3008853977)

Contact: **Hailey Hinkle**
Staff Regulatory Affairs Specialist
Phone: 510-413-2500
Email: hailey.hinkle@stryker.com

Date Prepared: August 31, 2020

Device Name and Classification:

Trade/Proprietary Name: Synchro SELECT™ Guidewire

Common Name: Wire, Guide, Catheter

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

Product Code: MOF, DQX

Legally Marketed Predicate Device

Primary Predicate Device	
K053268*	*PV 2000 Synchro^2 Guidewire*
Reference Predicate Device	
K190843	*Synchro^2 Support Guidewire*
K971254	*Transend EX Guidewire*

*K053268 was submitted to the FDA by Precision Vascular which was acquired by Boston Scientific which was then acquired by Stryker.

Device Description

Like the primary Predicate device, the Synchro SELECT Guidewire is a single-use product with a shapeable tip available in straight and pre-shaped configurations, used to gain intravascular access to 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.

The Synchro SELECT Guidewire comes in three stiffness profiles: Soft, Standard, and Support. The primary Predicate, PV 2000 Synchro^2 Guidewire (K053268), is only available in the Soft and Standard profiles. Therefore, the reference device, Synchro^2 Support (K190843), was included to support the similarity in technical characteristics to the Synchro SELECT Support stiffness profile. Certain design inputs and associated acceptance criteria for PV 2000 Synchro^2 (K053268) and Synchro^2 Support (K190843) were based on the reference device, Transend EX (K971254).

Accessories

The Synchro SELECT Guidewire is shipped with a Torque Device that is commercially available from Merit Medical (**K936032**), and a Guidewire Introducer that is commercially available from B. Braun (**K760389**).

Indications for Use

The Indications for Use for the Synchro SELECT Guidewire are the same as the primary Predicate PV 2000 Synchro^2 Guidewire and the reference Predicate Synchro^2 Support Guidewire and are as follows:

> The Synchro SELECT 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 neuro vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Technological Characteristics and Product Feature Comparison

The Synchro SELECT Guidewire is substantially equivalent to the Predicate device, the PV 2000 Synchro^2 Guidewire, cleared under **K053268,** based on the following:

- Same indications for use
- Same fundamental materials and manufacturing process
- Same fundamental design and technology
- Same operating principles
- Same biocompatibility information
- Same materials and processes for packaging
- Same sterilization method and process for devices

A comparison of the Subject device with the Predicate device is summarized in **Table 1** below.

Table 1. Product Feature Comparison of Subject Device to Predicate Device

	Predicate Device PV 2000 Synchro[2] Guidewire (K053268)	**Subject Device Synchro SELECT Guidewire**
Classification Name:	Wire, Guide, Catheter, 21 CFR 870.1330 – Class II	Same
Product Code	DQX	MOF, DQX
Review Panel	Neurology	Same
510(k) Submitter[1]:	Stryker Neurovascular 47900 Bayside Pkwy Fremont, CA 94538-6515	Same
Indications for Use	The PV 2000 Synchro[2] Guidewire series of products are intended for general intravascular use, including the neuro and peripheral vasculature. The device 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.	Same

[1] K053268 was submitted to the FDA by Precision Vascular which was acquired by Boston Scientific which was then acquired by Stryker.

	Predicate Device PV 2000 Synchro^2 Guidewire (K053268)	**Subject Device Synchro SELECT Guidewire**
Device Description/Principle of Operation	The PV 2000 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.	Same
Target Population	The PV 2000 Synchro^2 Guidewire series will be used in patients undergoing endovascular treatment including neurovascular and peripheral vasculatures.	Same
Accessories	Guidewire Introducer, Torque Device	Same
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	Standard and Soft: Platinum, 10cm Pre-shaped Support: Platinum, 7cm Straight Support: Platinum, 6cm

	Predicate Device PV 2000 Synchro^2 Guidewire (K053268)	**Subject Device Synchro SELECT Guidewire**
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	Commercially available per K760389	Same
Torque Device	Commercially available 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	Single Use/Sterile	Same

The differences between the devices do not raise new questions of safety and effectiveness.

Risk Assessment

Risk assessment of the Synchro SELECT Guidewire has been conducted in accordance with ISO 14971:2007. 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

Well-established test methods were used to evaluate the Subject device. All design inputs and associated acceptance criteria are identical to that of the primary Predicate (PV 2000 Synchro^2 Guidewire, K053268) and the reference device (Synchro^2 Support Guidewire, K190843). Some of the design inputs and associated acceptance criteria for PV 2000 Synchro^2 (K053268) and Synchro^2 Support (K190843) were based on the reference device, Transend EX (K971254). The results of confirmatory testing conducted on the Subject device demonstrate that it performs as designed and is suitable for its intended use. A summary of the tests performed on the Subject device is provided below in **Table 2**.

Table 2. Confirmation Testing Summary

Test	Test Method Summary	Conclusions
Coating Lubricity	Hydrophilic coating lubricity was assessed after 15 pull cycles through silicone pads.	All Synchro SELECT Guidewires met the specified coating lubricity requirements.
Coating Durability	Coating durability was assessed after repeated pull cycles through silicone pads (comparing degradation between Cycle 1-2 and Cycles 31-45).	All Synchro SELECT Guidewires met the specified coating durability requirements.

Test	Test Method Summary	Conclusions
Torque Response	Track the guidewire through a tortuous simulated use model and evaluate the steerability and torque response compared to the predicate.	All Synchro SELECT Guidewires demonstrated acceptable torque response. The torque response of the subject device was comparable to that of the predicate device.
Tip Shape-ability	Shape and un-shape the guidewire for a total of five times then visually inspect the distal tip for any fractures at 40x magnifications.	All Synchro SELECT Guidewires met the specified tip shape-ability requirements.
	Shape the tip of the guidewire to 90 degrees and record the tip shaping rating.	All Synchro SELECT Guidewires demonstrated acceptable tip shape-ability. The tip shape-ability of the subject device was comparable to that of the predicate device.
Tip Flexibility	Measure the force required to deflect the guidewire to a specified number of degrees at 20mm.	All Synchro SELECT Guidewires met the specified tip flexibility requirements.
Tensile Strength	Measure the force required to break the guidewire tip.	All Synchro SELECT Guidewires met the specified tensile strength requirements.
Torsional Strength	Record the number of times the proximal end of the wire can be rotated until it exceeds its maximum rotations and fails.	All Synchro SELECT Guidewires met the specified torsional strength requirements.
Flexure	Testing completed per ISO 11070:2014/A1: 2018, Annex G	All Synchro SELECT Guidewires met the specified flexure requirements.

Test	Test Method Summary	Conclusions
Fracture	Testing completed per ISO 11070:2014/A1: 2018, Annex F	All Synchro SELECT Guidewires met the specified fracture requirements.
Tip Integrity	Shape, straighten, and re-shape the guidewire in the opposite direction for a total of five times. Inspect at 40X for any fractures or breaks.	All Synchro SELECT Guidewires met the specified tip integrity requirements.
	Inspect the guidewire for any damage after tracking through a tortuous simulated use model.	All Synchro SELECT Guidewires demonstrated acceptable tip integrity after being tracked through a tortuous simulated use model.
Particulate Characterization	Count particulates of various size ranges after tracking through a tortuous simulated use model.	Particulate counts were reported and considered acceptable.
Hydrophilic Coating Integrity	Visually inspect and compare hydrophilic coating before and after tracking through a tortuous simulated use model. Additionally, visually inspect device coating after staining the devices.	All Synchro SELECT Guidewires met the specified hydrophilic coating integrity requirements.
Tip-shape Retention	Measure the tip shape retention after tracking the guidewire through a tortuous simulated use model.	All Synchro SELECT Guidewires demonstrated acceptable tip-shape retention. The tip-shape retention of the subject device was comparable to that of the predicate device.

Test	Test Method Summary	Conclusions
Tip Prolapse	Record the force required for the wire to buckle.	All Synchro SELECT Guidewires met the specified tip prolapse requirements.
Radiopacity	Subject and predicate guidewires evaluated under fluoroscopy.	All Synchro SELECT Guidewires demonstrated acceptable radiopacity. The radiopacity of the subject device was comparable to that of the predicate device.

Performance Data – Animal, Clinical

No animal or clinical studies were conducted as there is no change to the indications for use or the fundamental scientific technology. Substantial equivalence of the Subject device has been established to the Predicate devices through the results of bench testing.

Sterilization and Shelf Life Testing

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 ISO 11135:2014 ("*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 a standards assessment conducted by Stryker. A sterility assurance level (SAL) of 10^{-6} has been demonstrated.

There are no fundamental material changes compared to the predicate device. All components that are changing are metal, which are not affected by aging. There are no changes to existing shelf life. As with the Predicate device, the Synchro SELECT Guidewire is labeled with a 3-year shelf life.

Biocompatibility

Biocompatibility testing was conducted for the Predicate device **(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 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.

Conclusion

The Subject device is substantially equivalent to the 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.