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

July 18, 2017

Stryker Corporation
Mr. Nikin Desai
Regulatory Affairs Specialist
2 Pearl Court
Allendale, NJ 07401

Re: K171807
Trade/Device Name: ES2 Neuromonitoring Accessory Instruments
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: June 14, 2017
Received: June 19, 2017

Dear Mr. Desai:

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,

Michael J. Hoffmann -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

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)*
K171807

Device Name
ES2 Neuromonitoring Accessory Instruments

Indications for Use *(Describe)*
The ES2 Neuromonitoring instruments (Awls, Taps, Screwdriver and LITe Y-NEEDLE 200, 300 and 400) can be used by the surgeon to assist in location of the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws in open and percutaneous minimally invasive posterior surgical approaches of the non-cervical spine.

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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510(k) Summary: ES2® Neuromonitoring Accessory Instruments	
Manufacturer/Submitter:	Stryker Spine 2 Pearl Ct. Allendale, NJ 07401
Contact Person :	Name: Nikin Desai Phone: (201) 749-8176 Fax: (201) 831-3000 Email:Nikin.Desai@stryker.com
Date Prepared:	07/18/2017
Trade Name:	ES2 Neuromonitoring Accessory Instruments
Common Name:	Surgical Nerve Stimulator/Locator
Proposed Class:	Class II
Classification Name:	Surgical Nerve Stimulator/Locator (21 CFR §874.1820)
Product Code:	PDQ
Predicate Devices:	Primary Predicate: ES2 Spinal System Neuromonitoring Accessory Instruments (K140400)
Device Description:	The purpose of this submission is to introduce a line extension to the ES2 Neuromonitoring system to include the LITe Y-Needles. The ES2 Neuromonitoring instruments (Awl, Taps, Screwdriver and LITe® Y-NEEDLE 200, 300 and 400) are accessory instruments to be used with FDA cleared neuromonitoring systems to deliver electrical stimulation to assist in location of the spinal nerves during intraoperative neurological monitoring of the non-cervical spine in open and percutaneous minimally invasive posterior surgical approaches. The instruments are manufactured from surgical grade stainless steel and Acrylonitrile Butadiene Styrene (ABS). The Awls, taps and screwdriver are provided non-sterile. The LITe Y-Needles are sterile packed and single use devices that must be discarded after use. The neuromonitoring application is a surgical option that allows the surgeon to locate the spinal nerves by providing proximity information during targeting, bone preparation, and placement/insertion of bone screws. In addition to the neuromonitoring function: The LITe Y-Needles assist in targeting the pedicle and placing guidewires, the awl and taps facilitate bone preparation, and the screwdriver facilitates bone screw placement/insertion. The surgical accessories are compatible with commercially available FDA cleared neuromonitoring consoles/systems and associated electrodes. The nerves are stimulated using electrodes attached to the subject accessory devices. The screwdriver can be used with or without a powered option for bone screw placement.

510(k) Summary: ES2® Neuromonitoring Accessory Instruments	
Indications for Use:	The ES2 Neuromonitoring instruments (Awls, Taps, Screwdriver and LITe Y-NEEDLE 200, 300 and 400) can be used by the surgeon to assist in location of the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws in open and percutaneous minimally invasive posterior surgical approaches of the non-cervical spine.
Summary of the Technological Characteristics	The Stryker Spine ES2 Neuromonitoring Accessory Instruments are substantially equivalent to the predicate devices in terms of design, function, principals of operation, technological characteristics, and indications and intended uses. See table below for comparisons to predicate ES2 Neuromonitoring Accessory Instruments.
Summary of the Performance Data	See table below.
Conclusion	The risk analysis performed on the proposed addition of 200, 300 and 400 LITe Y-Needles to ES2 Neuromontoring and subsequent verification and validation activities demonstrate the line extension does not impact the ES2 Neuromonitoring Instrument's safety and effectiveness. Furthermore, the design verifications and validations performed as a result of the risk analysis and presented herein demonstrate the proposed device does not raise new questions of safety or effectiveness. Thus, the proposed modification and the predicate device are considered substantially equivalent.

Summary of the Performance Data		
Test	**Test Method Summary**	**Results**
Biocompatibility	A material biocompatibility evaluation was performed on the subject device in line with FDA guidance dated June 16, 2016 "Use of International Standard ISO 10993-1" and in accordance with ISO 10993-1:2009 and, Biological evaluation of medical devices – Part 1: Evaluation and Testing. The LITe Y-Needle is categorized as: • Externally communicating patient contacting with tissue/bone/dentin contact;limited exposure ≤24hrs	All samples passed acceptance criteria testing on subject device. The device demonstrated it had an acceptable biocompatibility profile commensurate with anticipated exposure.
Sterility and Packaging	Testing appropriate for the sterile packaged LITE Y-Needles device was performed as per the 2016 FDA Guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile", are sterilized using an "Established Category A" sterilization method, Gamma Radiation. This testing included but not limited to the following: • Physical stressing	All samples passed acceptance criteria testing on subject device and demonstrated that packaging and sterilization was appropriate for single use, sterile packaged devices.

Summary of the Performance Data		
Test	**Test Method Summary**	**Results**
	• Visual inspection • Seal strength • Bubble emission • Packaging aging	
EMC and Safety	Stryker Spine conducted Safety and EMC testing to evaluate the electrical performance and safety of the ES2 accessory instruments used for neuromonitoring applications. Safety tests were conducted and/or evaluated per IEC 60601-1.	EMC risk evaluation per IEC 60601-1 demonstrated that the subject device did not present a new worst case and met all applicable UL Safety and EMC tests.
Stationary Potential Generation Test	The purpose of this test is to verify that a potential stationary potential(s) produced when applying electrical current to the LITe Y-300 and Y-400 needles are not sufficiently large so false positive is not produced when used for neuromonitoring. The LITe® Y-Needle was placed in a biological simulant and connected to the stimulation probe. Recording probes and thermocouples were placed in the simulant. The LITe® Y-Needle was stimulated at clinical current levels for 60 seconds. Using a fixed sweep trace capture, the average stationary potential was obtained for the full duration.	The passing results of the stationary potential testing demonstrated that the LITe® Y-Needles generated a stationary potential less than or equal to the predefined acceptance criteria.
Electrical Resistance	The purpose of this test is to ensure the resistive and conduction sections of the needles are appropriate to allow for current conduction and current insulation during neuromonitoring. Probes were connected to the conductive and insulating portions of the device. The resistance of the conductive portion was measured. The resistance of the insulating portion was measured.	The passing results of the resistance test demonstrated that the LITe® Y-Needles experienced a resistance measurement less than or equal to the predefined acceptance criteria for conductivity and greater than or equal to the predefined acceptance criteria for the resistivity.
Current Variance	The purpose of this test is to verify the degree of current deviation along the axial length of the LITe® Y-Needle. This testing ensures the signal is conducted in a consistent manner as delivered by the neuromonitoring device. The LITe® Y-Needles were connected to stimulation probes at the conductive locations of the device. Clinical current levels were applied to the device for 10seconds, 100seconds, and 500 seconds. The transmitted current was recorded and compared to the applied current.	The passing results of the current deviation test demonstrated that the LITe® Y-Needles experienced a current deviation less than or equal to the predefined acceptance criteria.

Summary of the Performance Data		
Test	**Test Method Summary**	**Results**
Signal Conduction (amplitude change)	The purpose of this test is to verify the degree of signal loss the axial length of the LITe® Y-Needle. This testing ensures the signal is conducted in a consistent manner as delivered by the neuromonitoring device. The LITe® Y-Needles were connected to a stimulation probe at the conductive locations of the device. The device was stimulated using clinical current levels and the percentage difference of the power input was compared to the transmitted signal wave.	The passing results of the signal loss test demonstrated that the LITe® Y-Needles experienced a signal loss less than or equal to the predefined acceptance criteria.

Summary of the Technological Characteristics		
		Primary Predicate
Characteristics	**Subject device**	**ES2 Spinal System Neuromonitoring Accessory Instruments**
Manufacturer/OEM	Stryker Spine	Stryker Spine
510(k) Number	K171807	K140400
Product Code (Regulation number)	PDQ (21 CFR 874.1820)	ETN (21 CFR 874.1820)
Neuromonitoring Accessories Instruments	Awl, Taps, Screwdriver and 200,300 and 400 LITe Y-Needles	Awl, Taps, Screwdriver
Materials	Stainless steel, ABS and Radel	**Awl, Taps, and Screwdriver**: Surgical Grade Stainless Steel **Dilators and Tap Sleeve**- RADEL
Indications for use	The ES2 Neuromonitoring instruments (Awls, Taps, Screwdriver and LITe Y-NEEDLE 200, 300 and 400) can be used by the surgeon to assist in location of the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws in open and percutaneous minimally invasive posterior surgical approaches of the non-cervical spine.	Identical

Summary of the Technological Characteristics		
		Primary Predicate
Characteristics	**Subject device**	**ES2 Spinal System Neuromonitoring Accessory Instruments**
Surgical Approach	Open or Percutaneous/Minimally Invasive	Identical
How supplied (Sterile/Non-sterile)	200,300 and 400 LITe Y-Needles- Sterile Awls, Taps, and Screwdriver- Non-Sterile	Awls, Taps, and Screwdriver- Non-Sterile
Sterilization	The 200,300 and 400 LITe Y-Needles are provided as single-use sterile packaged devices. Non-sterile devices are provided with validated sterilization parameters to assure an SAL of 10^{-6}.	Non-sterile devices are provided with validated sterilization parameters to assure an SAL of 10-6.
Reusable or Single use?	200,300,and 400 LITe Y-Needles-Single use Awls, Taps, and Screwdriver- Reusable	Awls, Taps, and Screwdriver-Reusable
Use of Dilators	Dilators or Needle depth stop	Identical
Compatible with Common Neuromonitoring Consoles & Software	Compatible with FDA cleared neuromonitoring systems.	Identical
Connection to Neuromonitoring unit	Clip or Probe (based on Neuromonitoring System used)	Identical
IEC 60601 Compliant	Yes	Yes
Min. exposed surface area during tissue stimulation	$0.53mm^2$	$0.53mm^2$