JUL 0 1 2014

Section 008: 510(k) Summary

Proprietary Name:	ES2® Neuromonitoring Accessory Instruments
Common Name:	Surgical Nerve Stimulator/Locator
Classification Name and Reference:	21 CFR §874.1820: Surgical Nerve Stimulator/Locator
Device Product Code:	ETN
Proposed Regulatory Class:	Class II
For Information contact:	Soraya King Regulatory Affairs Specialist 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8296 Fax: (201) 962-4296 Email: Soraya.King@Stryker.com
Date Summary Prepared:	June 17, 2014
Predicate Devices	▪ NuVasive® NVM5 System – K112718 ▪ NuVasive® NVM5 System - K123307 ▪ Stryker Spine ES2® Spinal System – K122845
Device Description	The ES2® Neuromonitoring instruments (Awl, Taps, and Screwdriver) are accessory devices 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 are provided non-sterile. The neuromonitoring application is a surgical option that allows the surgeon to locate the spinal nerves by providing proximity information during bone preparation and placement/insertion of bone screws. The ES2® Awl and ES2® Taps facilitate bone preparation, and the ES2® 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 neuromonitoring accessory instrument can be used with or without a powered screwdriver option for bone screw placement.

Indication for Use	The ES2® Awl, ES2® Taps, and ES2® Screwdriver 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.
Intended Use	The ES2® Awl, ES2® Taps, and ES2® Screwdriver are intended to be used with the ES2® Dilators & ES2® Tap Sleeve during neuromonitoring applications. The neuromonitoring accessory instrument set-up is also intended to be used for bone screw insertion under power.
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. As compared to the NuVasive® NVM5® predicates, the ES2® Awl, ES2®Taps, and ES2® Screwdriver are cannulated to allow for K-Wire placement during percutaneous minimally invasive surgical approaches. The predicate NuVasive® NVM5® instruments and the ES2® Neuromonitoring Accessories are used with dilators and/or a tap sleeve to provide insulation. The electrical signal for both the NuVasive® NVM5® and ES2® instruments are supplied via electrodes (clip or probe) that are attached to the neuromonitoring contact zone of the awls, taps, or screwdrivers. In addition, the ES2® Screwdriver can be used with or without power for bone screw insertion. As FDA cleared in 510(k) #K122845, the power supply can be corded or cordless. Bench testing demonstrated that the ES2® Screwdriver can deliver safe and effective neuromonitoring signals using the non-powered or powered (corded and cordless) bone screw placement/insertion options.

COMPARISON OF ES2® NEUROMONITORING ACCESSORY INSTRUMENT AND THE PREDICATE DEVICE FOR NEUROMONITORING APPLICATIONS

Characteristic	**Subject Device: ES2® Neuromonitoring Accessory Instruments**	**Predicate Device: NuVasive® NVM5® System**	**Substantial Equivalence**
Neuromonitoring Accessories Instruments	Awl, Taps, and Screwdriver	Taps and Screwdriver	Yes - The ES2® and predicate system use the same types of accessory instruments for neuromonitoring applications during bone preparation/pilot hole starter and bone screw placement. The ES2® Neuromonitoring Accessory Instruments are employed and assembled in a similar manner with comparable set-up configurations to deliver electrical signals. Testing confirmed that the powered ES2® Screwdriver configuration does not interfere with the neuromonitoring signals and is safe and effective.
Use of Dilators	Dilators or Tap Sleeve	Dilators	Yes
Compatible with Common Neuromonitoring Consoles & Software	Compatible with FDA cleared neuromonitoring systems to include the NuVasive® NVM5® System	NuVasive® NVM5® System	Yes
Connection to Neuromonitoring unit	Clip or Probe (based on Neuromonitoring System used)	Clip	Yes – the use of a clip or probe is dependent on the neuromonitoring console and/or surgeon's preference. The clip or probe are attached to the accessory instrument on the exposed instrument contact area above the dilator or tap sleeve for both the ES2® and predicate devices.

Materials	**Awl, Taps, & Screwdriver:** Surgical Grade Stainless Steel **Dilators & Tap Sleeve:** RADEL®	Unknown	Yes – Instruments composed of well-characterized materials and accepted biocompatible materials.
Indication for Use	The ES2® Awls, ES2® Taps, and ES2® Screwdriver can be used 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 posterior surgical approaches of the non-cervical spine.	The NVM5® System is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. NVM5® provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial motor evoked potential (TceMEP) or somatosensory evoked potential (SSEP) responses of nerves. • XLIF (Detection) – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool. • **Basic & Dynamic Screw Test** – The Screw Test functions allow the surgeon to locate and evaluate the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws. • Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions. • Twitch Test (Train of Four) – The Twitch Test Function allows the	Yes – the indications of the ES2® Neuromonitoring Accessory Instruments are a subset of the indications of the predicate device. This does not result in a new or different intended use as compared to the predicate. The subject and predicate instruments are employed in the same manner when used as a tool to assist the surgeon in locating spinal nerves before, during, or after bone preparation and bone screw placement for open and percutaneous surgical approaches.

		surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses. • TcMEP – Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract. The TcMEP function provides an adjunctive method to allow the surgeon to monitor spinal cord motor pathway integrity during procedures with a risk of surgically induced motor injury. • SSEP – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk. • Remote Reader – The Remote Reader function provides real time remote access to the NVM5® System for monitoring physician outside of the operating room. • The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation producedure in the lumbar spine of adult patients, and when used in conjunction with radiographic imaging anatomy for the creation of a cannulation trajectory for bone screw placement.	
Sterilization	Instruments provided as reusable	As selected for individual accessories.	Yes

	non-sterile devices with validated sterilization parameters to assure a SAL of 10^{-6}	and validated to assure a SAL of 10-6	
Surgical Approach	Open or Percutaneous/Minimally Invasive	Open or Percutaneous/Minimally Invasive	Yes
Electromagnetic Compatibility & Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 61000-3-2 IEC 61000-3-3	IEC 60601-1-2	Yes
Min. exposed surface area during tissue stimulation	$0.53mm^2$	unknown	Yes – The test data demonstrated that the design of the subject device, the exposed surface area during tissue stimulation, and neuromonitoring instrument set-up/configurations do not impact or interfere with the electrical signaling and are comparable to the predicate devices.

Summary of the Performance Data	This 510(k) pre-market notification seeks expanded indications for the ES2® Awl, ES2® Taps, and ES2® Screwdriver to be used as accessory instruments during neuromonitoring applications. No design modifications, or changes in the materials of construction were made to the ES2® Awl, ES2® Taps, or ES2® Screwdriver, as previously presented in 510(k) #K122845, to facilitate neuromonitoring. All instruments are manufactured from surgical grade stainless steel. The materials of construction have been well characterized and shown to have stable chemical and mechanical properties that are not affected by aging or storage conditions. Performance testing was performed to demonstrate that the subject devices are substantially equivalent to the identified predicate instruments in terms of design, performance and intended use. The ES2® Neuromonitoring Accessory Instruments were tested for electrical safety in accordance with IEC 60601-1-2 for EMC and Safety. The instruments were also evaluated as per IEC 60601-1. A porcine animal study was conducted to assess the performance, functionality, and safety of the ES2® Neuromonitoring Accessory Instruments and implants utilizing the powered screw insertion option, corded and cordless. Bench test data and assessment confirmed substantial equivalence to the NuVasive® NVM5® predicates, and the safety and efficacy of the devices. Laboratory tests were conducted in compliance with applicable Good Laboratory Practices (GLP) requirements stipulated in 21 CFR Part 58.
Conclusion	Based on the information and comparison tables included in this 510(k), the ES2® Neuromonitoring Accessory Instruments are substantially equivalent to the NuVasive® NVM5® predicates. The instruments are employed in the same manner, have similar intended

	and indications for use, principles of operation, and technological characteristics. The ES2® subject devices met all required acceptance criteria and did not create new safety or efficacy concerns.

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 1, 2014

Stryker Spine
Soraya King
Regulatory Affairs Specialist
2 Pearl Court
Allendale, NJ 07401

Re: K140400
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: ETN
Dated: April 1, 2014
Received: April 2, 2014

Dear Ms. King:

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,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
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)*
K140400

Device Name
ES2® Neuromonitoring Accessory Instruments: ES2® Awl, ES2® Taps, and ES2® Screwdriver

Indications for Use *(Describe)*
The ES2® Awl, ES2® Taps, and ES2® Screwdriver can be used 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)

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)*

Felipe Aguel -S
Date: 2014.07.01 14:20:03 -04'00'

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."