MAR 2 7 2014

K132373

BIOMET
SPINE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	March 24, 2014
Applicant/Sponsor:	Biomet Spine 399 Jefferson Road Parsippany, NJ 07054
Contact Person:	Debra Bing Director, Regulatory Affairs Phone: 973-299-9300 x3964 Fax: 973-887-1347
Trade name:	Biomet Probes/Guidewires and Dilators
Device Class	Class II
Common Name:	Nerve Stimulator
Classification Name/Product Code	Surgical Nerve Stimulator/Locator - ETN PDQ
Device Panel - Regulation No.:	Ear, Nose & Throat - 21 CFR 874.1820

Device Description:

The Biomet insulated probes/guidewires and dilators are intended to dilate tissue and be used as intraoperative neuromonitoring (IONM) stimulation accessories by connecting to commercially available IONM equipment for locating and identifying peripheral nerves including spinal nerve roots during spinal surgery. The Biomet insulated probes/guidewires have a length of 305mm, an exposed stimulation area of .167 cm^2, and an outer diameter of 2.6mm. The Biomet insulated dilators have a length ranging from 229mm to 254mm, an exposed stimulation are of .167 cm^2, an inner diameter ranging from 3.2mm to 9.8mm, and an outer diameter ranging from 5.8mm to 13.8mm.

Predicate Device	Company Name	510(k) #
Cadwell Disposable Probes	Cadwell Labs Inc.	K103128
Cadwell Disposable Probes	Cadwell Labs Inc.	K123589
AVS® ARIA Neuromonitoring Probe & Dilators	Stryker Spine	K110419
Stimulation/Dissection Instruments	Nuvasive Inc.	K112709

Indications for Use:

The Biomet probes/guidewires and dilators are intended for tissue dilation and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery.

Summary of Technologies:

The proposed nerve stimulators are substantially equivalent to the predicate systems with respect to intended use and indications, materials, technological characteristics, and principles of operation. The predicate nerve stimulators are used with commercially available neuromonitoring equipment to deliver an electrical stimulus to locate peripheral and spinal nerve roots during spinal surgery. They are fabricated from similar biocompatible materials and are coated with an insulating material.

Substantial Equivalence:

The proposed probes/guidewires and dilators are substantially equivalent to the following legally marketed nerve stimulation devices in regards to intended use, fundamental technology, materials and operational principles and do not present any new issues of safety or effectiveness:

Substantial Equivalency Table				
	Biomet Access System	**Cadwell Disposable Probes**	**AVS® ARIA Neuromon. Probe & Dilators**	**Stimulation/Dissection Instruments**
	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Information				
Manufacturer	Biomet Spine (EBI LP)	Cadwell Labs, Inc.	Stryker Spine	Nuvasive, Inc
510(k) Number	K132373Pending	K103128 / K123589	K110419	K112709
Nerve Stimulation	✓	✓	✓	✓
Tissue dilation/dissection	✓	✓	✓	✓
Shaft Diameter	Ø2.6mm	Ø2.3mm	Ø2.1mm	n/a
Overall Length	305mm	215mm to 330mm		n/a
Electrical Connection	Passive	DIN	DIN	n/a
Monopolar	✓	✓	✓	n/a
Outer Diameter	Ø 5.8mm to Ø13.8mm	n/a	Ø6.4mm to Ø22.5mm	Ø6mm to Ø12mm
Inner Diameter	Ø3.2mm to Ø9.8mm	n/a	unknown	unknown
Overall Length	229mm to 254mm	n/a	~186mm to 206mm	unknown
Direct Electrical Connection	Passive	n/a	DIN	Passive
Monopolar	✓	n/a	✓	✓
Materials				
Stainless steel	✓	✓	✓	✓
Polymeric dielectric coating	✓	✓	✓	✓
Plastic handle	n/a	✓	n/a	n/a
Sterility Information				
Sterile packed	✓	✓		✓
Sold non-sterile			✓	
Principles of Operation				
Single use	✓	✓	✓	✓
Neuromonitoring during surgery	✓	✓	✓	✓
Tissue dilation/dissection during surgery	✓		✓	✓
Uncoated Conducting Surface Area	**.167 cm^2**	**.167 cm^2**	unknown	unknown
Charge Density Average (max)	**6.21 $\mu C/in^2$**	**6.21 $\mu C/in^2$**	unknown	unknown
Current Density Average (max)	**6.21 mA/in^2**	**6.21 mA/in^2**	unknown	unknown

✓ denotes substantial equivalence n/a=not applicable

Biocompatibility:

Biocompatibility testing was conducted on the Biomet insulated probes/guidewires and dilators in accordance with the testing recommendations in ISO 10993-1 (Biological Evaluation of Medical Devices Part 1: Evaluation and Testing). The test results are summarized in the table below.

Tests	Results	Conclusion
Cytotoxicity	No evidence of cytotoxicity	Non-cytotoxic
Sensitization	No evidence of sensitization	Non-sensitizing
Irritation	No evidence of irritation	Non-irritant
Systemic Toxicity	No signs of toxicity	No systemically toxic
Pyrogen Test	No signs of pyrogens	Non-pyrogenic

As shown in the table, biocompatibility testing found the Biomet insulated probes/guidewires and dilators to be non-cytotoxic, non-irritant, non-sensitizing, no systemically toxic, and non-pyrogenic.

Performance Data:

Bench testing was conducted to demonstrate that the subject nerve stimulators are substantially equivalent to the predicate devices. The following bench testing was performed:

- Total Resistance,
- System Impedance,
- Current Density, and
- Mechanical/Electrical Testing

The results demonstrate that the subject nerve stimulators are equivalent the predicate device and do not raise any issues of safety or effectiveness. In addition, biocompatibility testing was conducted and has demonstrated that the subject nerve stimulators are biocompatible.

The Biomet probes/guidewires and dilators conform to the following standards:

Materials

ASTM F899:2012 - Standard Specification for Wrought Stainless Steels for Surgical Instruments (Recognition List 030, Recognition No. 332)

Sterilization

AAMI/ANSI/ISO 11137-2:2006 - Sterilization of Healthcare Products: Radiation- Part 2: Establishing Sterilization Dose (Recognition List 028, Recognition No. 14-225)

ANSI/AAMI ST79: 2010 & A1:2010 (Consolidated Text) - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (Recognition List 027, Recognition No. 14-312)

AAMI TIR 30: 2003 - A Compendium of Processes, materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices (Note: This not a FDA recognized standard but it is considered a relevant standard.)

ANSI/AAMI/ISO 11135-1:2007 - Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices (Recognition List 028, Recognition No. 14-228)

Testing

ASTM D149: 2009 - Standard Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies (Not recognized)

ASTM D4169: 2009 - Standard Practice for Performance Testing of Shipping Containers and Systems (Recognition List 030, Recognition No. 14-300)
9-8 ASTM D5276: 1998 (2009) - Standard Test Method for Drop Test of Loaded Containers by Free Fall (Not recognized)

ASTM D999: 2008 - Standard Test Methods for Vibration Testing of Shipping Containers (Not recognized)

Biocompatibility

ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for *in vitro* cytotoxicity

ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

ISO 10993-11, Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity

FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58

"ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing Within a Risk Management Process. 4th ed. 2009-10-15"

Conclusion:

The subject devices are substantially equivalent to the predicates, when used in as tissue dilators and nerve stimulators. Mechanical and electrical testing along with other supporting information sufficiently demonstrates the substantial equivalence of the subject device to the other commercially available nerve stimulators. Based on this information, the subject devices do not raise any new issues regarding the safety or efficacy, when used to dilate tissue or as a nerve locator.

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

March 27, 2014

Biomet Spine
Ms. Vivian Kelly
Regulatory Affairs Project Manager
399 Jefferson Road
Parsippany, New Jersey 07054

Re: K132373
Trade/Device Name: Biomet Access System
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical Nerve Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: 2/6/2014
Received: 2/7/2014

Dear Ms. Kelly:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -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 on last page.

510(k) Number *(if known)*
K132373

Device Name
Biomet Probes/Guidewires and Dilators

Indications for Use *(Describe)*

The Biomet probes/guidewires and dilators are intended for tissue dilation and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery.

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)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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