March 22, 2018

Medos International SARL
% Sheree Geller
Regulatory Affairs Specialist
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K173134
Trade/Device Name: SENTIO MMG Pedicle Access Needles
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: February 20, 2018
Received: February 21, 2018

Dear Sheree Geller:

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.

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173134

Device Name
SENTIO MMG Pedicle Access Needles

Indications for Use *(Describe)*
The SENTIO MMG Pedicle Access Needles are indicated for use in pedicle pilot hole preparation and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

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.

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."

510(K) SUMMARY

A. Submitter Information

Manufacturer:	Medos International SARL Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Synthes Spine 325 Paramount Drive Raynham, MA 02767
Contact Person:	Sheree Geller 325 Paramount Drive Raynham, MA 02767
Telephone:	(508) 828-3291
Fax:	(508) 828-3797
Email:	sgeller1@its.jnj.com

B. Date Prepared

March 22, 2018

C. Device Name

Trade/Proprietary Name:	SENTIO MMG® Pedicle Access Needles
Common/Usual Name:	Nerve Stimulator/Locator
Classification Name:	21 CFR §874.1820 Surgical nerve stimulator/locator
Regulatory Class:	II
Product Code & Review Panel:	PDQ; Neurology

D. Predicate Device Names

Primary Predicate:	NeuralMAS™ (K100992)
Additional Predicate:	NuVasive® Stimulation/Dissection Instruments (K112709)

E. Device Description

The SENTIO MMG Pedicle Access Needles are surgical instruments that incorporate insulated probes with standard connectors to ensure maximum ease of use and compatibility with the Sentio MMG Nerve Mapping and Avoidance System for use during surgeries in which a motor nerve is at risk. The SENTIO MMG Pedicle Access Needles are utilized for pedicle preparation in spine surgery with application of dynamic stimulation for nerve detection. They are provided sterile (ethylene oxide) and have two components: Needle (cannula and trocar) and 2.5m Stimulation Cable. The cannula is marked with equidistant reference depth markers (1cm) relative to the distal [to user] end.

F. Intended Use

The SENTIO MMG Pedicle Access Needles are indicated for use in pedicle pilot hole preparation and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

G. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The intended use and technological characteristics, including material, design, and performance, of the SENTIO MMG Pedicle Access Needles are consistent with those of the predicate devices.

	Predicate Devices		**Subject Device**	**Substantially Equivalent**
	NeuralMAS™ (K100992)	NuVasive® Stimulation/Dissection Instruments (K112709)	SENTIO MMG® Pedicle Access Needles	
Intended Use	NeuralMAS is intended for use in surgical procedures to assist in locating and mapping motor nerves through the use of mechanomyographic (MMG) signals and electrical stimulus of nerves. This device is indicated for locating and identifying spinal nerve roots and peripheral motor nerves origination from spinal levels C3-T1 and L2-S2.	The Stimulation/Dissection Instruments are indicated for tissue dissection and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	The SENTIO MMG® Pedicle Access Needles are indicated for use in pedicle pilot hole preparation and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	Yes
Product Code	ETN	ETN	PDQ	Yes
Regulation	21 CFR §874.1820	21 CFR §874.1820	21 CFR §874.1820	Yes
Electrical Insulation	The sterile stimulation instruments have biocompatible electrical insulation applied to select portions. The distal surfaces of the instruments are selectively non-insulated stainless steel to provide for mechanical, manual dissection, probing, cannulation, and tissue stimulation.	Some instruments have electrical insulation on surfaces not intended to provide electrical contact with the patient and connection while others are used with an insulation accessory that provides electrical insulation on surfaces not intended to provide electrical contact with the patient and connection.	The subject devices have biocompatible electrical insulation applied to select portions. The distal surfaces of the instruments are selectively non-insulated stainless steel to provide for mechanical, manual dissection, probing, cannulation, and tissue stimulation.	Yes
Proximal Stimulator Connector	Yes	Yes	Yes	Yes
Patient Contacting Material	Biocompatible: Stainless Steel Parylene C	Biocompatible: Stainless Steel, Anodized Aluminum Radel	Biocompatible: Stainless Steel Parylene C	Yes
Delivery	Sterile for single use	Some instruments are provided sterile for single use only while others are provided as non-sterile reusable instruments.	Sterile for single use	Yes

H. Materials

The patient contacting materials of the subject devices are biocompatible stainless steel with Parylene C conformal coating.

I. Performance Data

Non-clinical testing was conducted to demonstrate the safety and effectiveness of the subject devices. The SENTIO MMG Pedicle Access Needles were evaluated as follows:

Characteristic	Evaluation Summary	Conclusion
Durability	Durability testing served to determine that materials and mating interfaces of the subject device survive the force of entering the pedicle, the interface between the top and bottom handles remains intact, the stylet is sufficiently sharp to pass through bone, and the needle cannula beveled edge is sufficient to dig into bone. Testing was completed using simulated bone material.	All samples passed the acceptance criteria. The durability of the subject device has been determined substantially equivalent to the predicate.
Wire to Plug Connection	The wire to plug connection of the subject device was tested for tensile force resistance. The plug from the connection wire component part was inserted into a test sample intended to accommodate a resistance fit. The sample construct was subject to tensile force until the wire disconnected from the sample handle.	All samples passed the acceptance criteria. The subject device connection assembly has been determined substantially equivalent to the predicate.
System Compatibility	Needle stimulation testing was conducted to verify that the subject device maintains compatibility with the NeuralMAS™ (K100992) predicate, and provides electrical isolation such that energy delivery is focused from only the distal tip of the needle.	Test results demonstrated subject device compatibility with the predicate NeuralMAS™ (K100992) system.
Electrical Stimulation	The subject device was tested for compatibility with electrical stimulation sources of 100V, 200V, and 300V.	Compatibility with electrical stimulation sources was verified, supporting substantial equivalence of the subject device.
Biocompatibility	Per ISO 10993-1, the subject device is categorized as an external communicating device for tissue/bone contact of limited duration. The Parylene C conformal coating remains unchanged from the NeuralMAS™ (K100992) predicate. Stainless Steel has a history of clinical use and biocompatibility; cleaning validations were conducted to confirm removal of processing reagents.	The biocompatibility of the subject device has been assessed as substantially equivalent to the predicate.
Sterility	The ethylene oxide sterilization method was validated per ISO 11135-1 for the subject device. Sterilization residual levels were tested for compliance to ISO 10993-7.	The subject devices will be provided sterile with a SAL of 10^{-6}. The sterilization residual levels were determined compliant with ISO 10993-7 for limited exposure devices. Delivery state of the subject device is determined to be substantially equivalent to the predicate.

J. Conclusion

Evaluation of the subject device intended use, technological characteristics, and performance data demonstrates substantial equivalence with the predicate devices.