April 5, 2018

Medos International, SARL
℅ Anna D'lima
Senior Regulatory Affairs Program Lead
DePuy Synthes
325 Paramont Drive
Raynham, Massachusetts 02767

Re: K173526
Trade/Device Name: SENTIO MMG Gen 2
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: March 1, 2018
Received: March 5, 2018

Dear Anna D'lima:

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,

William J. Heetderks -S
2018.04.05 16:43:21 -04'00'

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)*
K173526

Device Name
SENTIO MMG Gen 2

Indications for Use *(Describe)*
This device 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. The device provides information directly to the surgeon to help assess a patient's neurophysiologic status by measuring and comparing MMG signals throughout a surgical procedure.

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.

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medos international

510(K) SUMMARY K173526

A. Submitter Information

Manufacturer:	Medos International SARL Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02767
Contact Person:	Anna D'Lima 325 Paramount Drive Raynham, MA 02767
Telephone number:	508-977-3896
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Email:	adlima@its.jnj.com

B. Date Prepared

April 02, 2018

C. Device Name

Trade/Proprietary Name:	SENTIO MMG® Gen 2
Common/Usual Name:	Surgical Nerve Stimulator/Locator
Device Classification and Regulation:	Class II per 21 CFR §874.1820
Product Code and Description:	PDQ; Neurosurgical Nerve Locator ETN; Stimulator, Nerve

D. Predicate Device Name

Primary:	SENTIO MMG (K131304)
Other:	NuVasive Next Generation NVM5 System (K162313), STIMPOD NMS450 Nerve Stimulator (K102084)
Reference Device:	NIM-Spine (K031510), predicate to original SENTIO MMG submission (K100992)

E. Device Description

SENTIO MMG Gen 2 is a multichannel device for locating, mapping and assessing the status of motor nerves during surgical procedures. SENTIO MMG Gen 2 alerts the user of recorded mechanical activity (termed mechanomyography, or MMG) from muscles innervated by affected nerves, which may originate from operator applied electrical stimulus or unintentional innervation of the nerve as a result of nerve impact, retraction, compression, or other mechanical factors. The device will assist with nerve identification and assessment by alerting the surgeon when monitored nerves are activated. The device will also assist with tracking the status of monitored nerves throughout the course of surgical intervention. The Sentio MMG Gen 2 system consists of capital equipment and disposable devices, both sterile and non-sterile.

F. Technological Characteristics

Stimulus Modes	**Standard (Monopolar)**	**Bipolar**	**Train of Four**
Current Ranges	0-20 mA	0-2 mA	20-80 mA
Current Adjustment	1 mA	0.1 mA	5 mA
Stimulation Voltages	115 V	27 V	350 V
Waveform	Monophasic square pulse	Monophasic square pulse	Monophasic square pulse
Pulse Width	50-250 µs	50-250 µs	100-200 µs
Pulse Rate	4 Hz, Continuous	4 Hz, Continuous	2 Hz, 4 Pulse burst
Nerve Mapping Probe	Single-use, sterile accessory used to provide electrical stimulation to the surgical site		
MMG Sensor	Single-use, non-sterile three-dimensional accelerometer designed to provide feedback for locating and mapping motor nerves		
AC Power Supply	Delta MDS-060AAS12 B		
Weight	Tablet: 0.68 Kg Control Unit: 0.72 Kg		
Dimensions	Tablet: 291 mm (D) x 193 mm (W) x 8 mm (H) Control Unit: 220 mm (D) x 140 mm (W) x 40 mm (H)		

G. Indications for Use / Intended Use

This device 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. The device provides information directly to the surgeon to help assess a patient's neurophysiologic status by measuring and comparing MMG signals throughout a surgical procedure.

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

The intended use and technological characteristics, including material, design, and performance, of SENTIO MMG Gen 2 are consistent with those of the predicate device. The different user interface and enhanced MMG signal acquisition do not raise new questions of safety and effectiveness based on results of bench testing and comparative performance evaluation.

Attribute	Substantial Equivalence Evaluation
Indications for Use	Substantially equivalent - The indications for use statement for the SENTIO MMG Gen 2 is a combination of the primary and secondary predicate devices. The differences do not change the intended use as a surgical nerve stimulator / locator, nor raise new questions of safety or effectiveness as demonstrated by results of the risk-based verification and validation testing.
Capital Equipment: Control Unit and PC/Display Capital Equipment: Control Unit and PC/Display (continued)	Number of Channels - Enhanced signal acquisition in comparison to primary predicate - Substantially equivalent to secondary predicates for same purpose of detecting a muscle event as evidenced by comparative performance evaluation. User interface - Touchscreen Tablet PC - Same as the primary predicate, substantially equivalent to secondary predicates with the same functional specification (system operation). Display Size - Substantially equivalent - Subject device meets the same acceptance criteria and conforms to the same consensus standards as the primary predicate device. Weight - Substantially equivalent - Subject device meets the same acceptance criteria and conforms to the same consensus standards as the primary predicate device. Audio - Same as primary predicate and substantially equivalent to secondary predicates.
System Stimulation	Type Constant - Constant Current (mA) - Same as primary predicate. Stimulus Range - Standard (monopolar), Bipolar Mode, Train of Four - Substantially equivalent - Ranges are the same, or within, the ranges of the primary predicate device, secondary predicates, or reference device and have the same intended function. Control - Digitally controlled, incremental adjustment - Standard (monopolar), Bipolar Mode, Train of Four, or selectable range via touchscreen - Same as primary predicate. Maximum Stimulation Voltage - Substantially equivalent - Maximums are within the limit settings of the primary predicate device, secondary predicates, or reference device and have the same intended function. Waveform - Monophasic square pulse - Same as primary predicate. Pulse Width - Standard (monopolar), Bipolar Mode, Train of Four - Same as primary predicate - Substantially equivalent - Ranges are the same, or within, the ranges of the primary predicate device, secondary predicates, or reference device and have the same intended function. Stimulation Rate - Same as the primary predicate and the same or less than the secondary predicates and reference device.

Attribute	Substantial Equivalence Evaluation
	Activation - Touchscreen or hand switch - Same as the primary predicate.
Sensors	Signal (electromechanical) - Same as primary predicate. Attachment Site - Skin surface - Same as primary predicate. Size - Reduced size for smaller site attachment - Same performance criteria with reduced site attachment. Connector type - 3.5mm Stereo plug - Substantially Equivalent - 3.5mm plug is independent of orientation. Same performance requirements. Technology - Digital - Substantially Equivalent as evidenced by comparative performance evaluation. Operating Voltage - 1.8V compared to 3.3V - Substantially Equivalent - lower power consumes less energy for operation yet meets the same performance.
Stimulator Probe	Same as primary predicate.
Ground Patch	Attachment Site - Skin surface - Same as primary predicate. Size - Same as primary predicate. Connector Type - 1.5mm touch proof - Industry standard DIN 42-802.
Materials	Capital equipment is comprised of materials evidenced to be suited for their specified purpose. Stimulator Probe is biocompatible and the same as the primary predicate. Sensors are biocompatible and comprised of the same, or proven equivalent materials. Ground Patch is biocompatibility and comprised of the same, or proven equivalent materials.

I. Performance Data

Non-clinical testing was conducted in accordance with Design Controls and Risk Management to confirm device performance for its intended use. The test results demonstrate that the device performs as well as the predicate devices and/or conform to recognized consensus standards for the compared design inputs, including, but not limited to; operating conditions, electrical safety, electromagnetic compatibility, hardware and disposable device functionality, signal acquisition equivalence, comparative performance evaluation using clinically relevant MMG signal simulation to capture a statistically significant sample to demonstrate high agreement with respect to performance of the primary predicate, biocompatibility, shelf-life, sterilization, packaging integrity, and software validations.

J. Conclusion

The indications for use and intended use of the subject device are consistent with those of the predicate devices. Comparison of technological characteristics and results of performance testing demonstrate substantial equivalence with the predicate devices.