DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 1, 2016

Inomed Medizintechnik Gmbh
Saschka Busch
Quality Management and Regulatory Affairs
Im Hausgruen 29
Emmendingen Baden- Wuerttemberg, D- 79312 DE

Re: K152505
Trade/Device Name: C2 NerveMonitor System
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN, GWF
Dated: October 30, 2015
Received: November 3, 2015

Dear Mr. Busch:

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 yours,

Eric A. Mann -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat 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)*
K152505

Device Name
C2 NerveMonitor System

Indications for Use *(Describe)*
The C2 NerveMonitor System is intended for intra-operative monitoring and stimulation for localization and identification of cranial and peripheral motor and mixed motor sensory nerves during surgery, including spinal nerve roots. The C2 NerveMonitor device with the integrated user interface is only allowed for the surveillance, documentation and functional test of motor nerves. It can be used as an additional helping tool during surgical procedures for diagnostic issues. Its basic functions are similar to those of an EMG diagnostic device.

Indications for C2 NerveMonitor System Monitoring Procedures include:
Extracranial, Intratemporal, Extratemporal, Neck Dissections, and Upper and Lower Extremities.

Indications for C2 NerveMonitor System monitoring of Spinal procedures include:
Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Orthopedic Surgery, Open and Percutaneous Lumbar and Cervical Surgical Procedures.

The system is not intended for monitoring life preserving functions.
The system may not be used for diagnosing brain death.

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

	Contact Information
510(k) Submitter	inomed Medizintechnik GmbH Im Hausgruen 29 Emmendingen Baden-Wuerttemberg Germany Ph: +49 7641 / 94 14-87 Fax: +49 7641 / 94 14-94
FDA Establishment Registration No.	3004753785
Contact Person	Saschka Busch Ph: +49 7641 / 94 14-87 Fax: +49 7641 / 94 14-94 s.busch@inomed.com
Date Prepared	October 30, 2015
	***Subject* Information**
Trade Name	C2 NerveMonitor System
Common Name	Nerve monitor
Classification	II, non-exempt
Classification Name and Product Code	Stimulator, Nerve (21 CFR 874.1820, Product code ETN); Stimulator, Electrical, Evoked Response (21 CFR 882.1870, Product code GWF).

Predicate Information

510(k) Number	Product Code	Trade Name	Manufacturer
K111647	ETN, GWF	C2 NerveMonitor System	inomed Medizintechnik GmbH

Device Description

The C2 NerveMonitor System performs intraoperative neurophysiologic monitoring (IONM) for localization and identification of cranial and peripheral motor and mixed motor sensory nerves during surgery, including spinal nerve roots. The C2 NerveMonitor device with the integrated user interface is only allowed for the surveillance, documentation and functional test of motor nerves. It can be used as an additional helping tool during surgical procedures for diagnostic issues. Its basic functions are similar to those of an EMG diagnostic device. The system is not intended for monitoring life preserving functions.

The subject device stimulates for evoked responses, records, measures, and provides visual and auditory outputs for the physiological responses received from the patient. The response signals may be stimulated evoked responses or spontaneous electrophysiological action potential

signals. The subject software calculates the signal amplitude and latency. The subject device provides a visual display and auditory tones corresponding with the actions performed or signals received. The waveforms are stored in the device internal memory. The user may review the signals after surgery in printed or electronically exported report formats.

The C2 NerveMonitor System consists of 4 and 8 Channel C2 NerveMonitor consoles and an optional iPad application as subject of this submission. The system also includes stimulation probe and recording electrodes, laser printer, adapter box, cables, WiFi router, sterile iPad cover, mute sensor, footswitch, and keyboard accessories that are not subject to this submission.

The C2 NerveMonitor consoles consist of software, hardware, and electrical components. The software has been updated and is subject to this submission. The software updates introduce optional device connectivity and the signal peak detection algorithm. The connectivity allows for Hospital Information System (HIS) Ethernet network interface, and wireless connection via iPad application. The signal peak detection algorithm supports channel select, synthetic sound, and quantitative measurements displayed during signal receipt features.

Indication for Use

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Technological Characteristic Comparison Summary		
Characteristic	**Predicate Device (K111647)**	**Subject Device**
Type of Use	Prescription use only	No change
Condition for Use	Reusable (capital equipment)	No change
Sterility	Non-sterile	No change
Console	Display screen, soft keys (buttons), and rotary controls on front panel of console	No change
Mode/ Mechanism of Action	• Transfers electrical energy to stimulate for evoked responses • Intraoperatively receives and records stimulated evoked responses or spontaneous electrophysiological action potential signals from the patient	No change
Power	100V – 240V (Volts) and 50/60Hz (Hertz) electrical outlet connection	No change
Signal Response Output	Visual and auditory	No change
Workstation	Standard personal computer (PC) components	No change
Printer Capacity	Waveform data can be printed on an external printer	No change
Electrical Safety	Type BF, Class I	No change
System Compatibility	Stimulation probes and recording electrodes	No change
		EMG Recording Software Unit
Available Channels	4, 8	No change
Measurement Range	0.800µVpp - 800µVpp (microvolts peak-to-peak)	No change
Resolution	16Bit	No change
Sampling Rate	20kHz	No change
Blanking	1ms - 4ms	No change
Maximum Tolerance	10%	No change
		Stimulation Software Unit
Available Channels	2	No change
Frequency	3Hz / 30Hz, programmable in the range of 1Hz - 30Hz	No change
Polarity	Unipolar, negative rectangular pulse	No change
Pulse width	Fixed 200µs	No change
Type	Constant current	No change

Technological Characteristic Comparison Summary		
Characteristic	**Predicate Device (K111647)**	**Subject Device**
Current	0.01mA - 25mA	No change
Voltage	100V	No change
Maximum Tolerance	±10%, ±1 digit (0.01mA)	No change
		Software
Operating System	Windows XP Embedded – Off-The-Shelf (OTS), Service Pack 3	No change
Software Version	C2 Software Version 1.3	C2 Software Version was updated to 3.0. The update introduces optional device connectivity and software changes as described in the Device Description.

Performance Data

Nonclinical

The changes subject to this 510(k) include software modifications only. Non-clinical verification and validation testing performed with the subject device focused on the software changes implemented, and evaluated overall system performance.

The software changes have been tested in accordance with the inomed software development life cycle procedure. Verification and validation testing activities were performed at the software system and component levels to show sufficient implementation of the changes as per the specifications.

Software testing conducted includes:

- System level software verification
- EMG record triggered peak detection verification
- Peak detection validation
- HL7 integration verification
- Off-the-shelf NetOp OnDemand software qualification
- Software update verification
- Factory settings verification

Overall performance test was performed to evaluate the subject device software, hardware, and electrical components. This test was utilized to verify that the subject device performs as intended after the changes implemented.

The verification and validation testing results demonstrate all requirements were fulfilled. The software testing was performed with the latest software version 3.0, and on production equivalent versions of the C2 NerveMonitor. The testing was relevant and the results met the pre-defined acceptance criteria. The testing results confirm the changes meet the pre-defined specifications and do not raise different questions of safety and effectiveness for the subject devices.

Clinical
Clinical testing was deemed not required to support the safety and effectiveness of the subject device for the intended use.
Conclusion
The intended use, basic design, and fundamental scientific technology are identical between the subject C2 NerveMonitor System and the predicate. The subject change introduces software changes to the predicate including optional device connectivity and the signal peak detection algorithm. Cybersecurity risk control measures appropriate for the subject device and intended use environment have been implemented. Verification and validation testing results confirm there are no different questions of safety or effectiveness. The changes do not constitute a new intended use, and do not affect the control mechanism, operating principle, or energy type. The information presented in this notification supports the subject devices to be as safe and effective as the predicate, and therefore supports a determination of substantial equivalence.