January 27, 2023

Inomed Medizintechnik GmbH
Anja Riesterer, M.Sc.
Regulatory Affairs Manager
Im Hausgruen 29
Emmendingen, 79312
Germany

Re: K223254
Trade/Device Name: C2 Xplore
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN, GWF
Dated: October 14, 2022
Received: October 21, 2022

Dear Anja Riesterer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223254

Device Name
C2 Xplore

Indications for Use *(Describe)*
The C2 Xplore is designed for use in the operating room to measure and display the neurophysiological signals.
The system supports the application of Electromyography (EMG) for the purposes of intraoperative neuromonitoring of the peripheral nervous system.
The system is not intended for monitoring life-sustaining functions.

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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510(k) Summary

Submission Date:	2022-10-14	
Subject 510(k) number	K223254	
510(k) Holder:	inomed Medizintechnik GmbH Im Hausgruen 29 79312 Emmendingen, Germany	
Submitter and Application Correspondent:	Maximilian Wimmer Phone: +49 7641 6414 545 Email: m.wimmer@inomed.com	
Manufacturing Site:	inomed Medizintechnik GmbH Im Hausgruen 29 79312 Emmendingen, Germany	
Trade Name:	C2 Xplore	
Classification Regulation:	Surgical nerve stimulator/locator 21 CFR §874.1820	
Product Code:	ETN, GWF	
Regulation Medical Specialty:	Ear, Nose, and Throat	
Substantially Equivalent Devices:	Predicate device 510(k) number K152505	Predicate device Manufacturer/ Model inomed Medizintechnik GmbH C2 NerveMonitor System
	Reference device 510(k) number K083124	Reference device Manufacturer/ Model Medtronic Xomed, Inc Nerve Integrity Monitor 3.0

Device Description:	The C2 Xplore is an electromyography (EMG) monitor for the purposes of intraoperative neuromonitoring of the peripheral nervous system. The C2 Xplore assists the surgeon in nerve identification, helping to locate and identify nerves at risk in the surgical field. The device records the EMG activity from the innervated nerves and provides visual and audible feedback for the surgeon, helping to preserve the nerve structures throughout the procedure. The device is equipped with 8 differential amplifier channels and with two independent stimulators. The C2 Xplore is operated via mechanical turning knobs and a touchscreen on the front. The audio feedback is generated by an integrated loudspeaker. The nerve monitoring provides information about the amplitude and latency of the EMG responses.
Intended Use of Subject Device: C2 Xplore	The C2 Xplore is intended for intraoperative neuromonitoring; for recording of electrophysiological signals and stimulating of nerve and muscle tissues.
Indications for Use of Subject Device: C2 Xplore	The C2 Xplore is designed for use in the operating room to measure and display the neurophysiological signals. The system supports the application of Electromyography (EMG) for the purposes of intraoperative neuromonitoring of the peripheral nervous system. The system is not intended for monitoring life-sustaining functions.
Intended Use of Predicate Device: C2 NerveMonitor System K152505	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.
Indications for Use of Predicate Device C2 NerveMonitor System K152505	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.

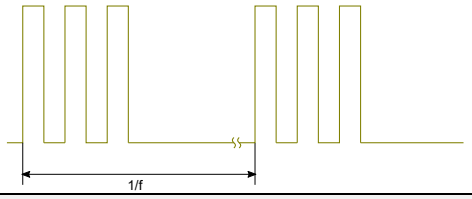
Conclusion of the intended use evaluation:

inomed Medizintechnik GmbH claims that the predicate and subject devices are substantially equivalent in terms of the intended use and indications for use. Both the predicate and subject devices can be used for the recording of electrophysiological signals and stimulating nerve and muscle tissues for intraoperative neuromonitoring.

Technology Comparison:

The technological characteristics of the C2 Xplore and the predecessor device (predicate device) are equivalent.

	Subject device	**Predicate device**
System	C2 Xplore	C2 NerveMonitor System
Manufacturer	inomed Medizintechnik GmbH	inomed Medizintechnik GmbH
Energy Type		
Power	100 V – 240 V and 50/60 Hz electrical outlet connection	100 V – 240 V and 50/60 Hz electrical outlet connection
Performance Specifications – EMG Recording Unit		
Measurement principle	Amplifiers based on differential (bipolar) type of recording	Amplifiers based on differential (bipolar) type of recording
Recording channels	8 differential channels	8 differential channels
Measurement range	1 mVpp – 500 mVpp (programmable)	800 µVpp – 800 mVpp (programmable)
A/D resolution	16-bit	16-bit
Common-mode rejection ratio (CMRR)	> 100 dB (50 Hz)	> 100 dB (50 Hz)
Input noise level	< 1.5 µVEff (with hardware filter 30 Hz to 2.5 kHz)	< 1.2 µVEff (with hardware filter 30 Hz to 1.25 kHz)
Input Impedance	> 100 MΩ	> 100 MΩ
Hardware bandpass	0.5 Hz – 5 kHz	0.5 Hz – 5 kHz
Scanning rate	20 kHz	20 kHz
Blanking	1 – 4 ms	1 – 4 ms
Performance Specifications – Stimulation Unit		
Stimulation channels	2	2

Frequency	Programmable 0.1 – 30 Hz	Programmable 1 – 30Hz
Polarity	Unipolar, negative rectangular pulse	Unipolar, negative rectangular pulse
Voltage limit	100 V	100 V
Load Impedance	0 – 10 kΩ	0 – 10 kΩ
Current sensor	Display of current flow (confirm current)	Display of current flow (confirm current)
Visual Output	Visual display shows waveform amplitude and latency time of stimulated and recorded signals	Visual display shows waveform amplitude and latency time of stimulated and recorded signals
Stimulation parameters		
Stimulation intensity (I) and pulse width (PW)		
Stimulation frequency (f) range		
Stimulator 1 (direct nerve stimulator)		
Frequency (f)	Programmable 0.1 – 30 Hz	Programmable 1 – 30Hz
Pulse width (PW)	200 µs	200 µs
Current (I)	0.01 – 5 mA	0.01 – 5 mA
Maximum RMS stimulation intensity	0.39 mA	0.39 mA
Minimum electrode size	0.001 cm²	0.001 cm²
Maximum current density	390 mA/cm²	390 mA/cm²
Maximum power density	25 W/cm²	25 W/cm²
Maximum charge density	78 µC/cm²	78 µC/cm²
Stimulator 2 (continuous stimulator in combination with Medtronic APS electrode)		
Frequency (f)	max. 2 Hz	Predicate device: --- Reference device: max. 2 Hz
Pulse width (PW)	100 µs	Predicate device: --- Reference device: 100 µs
Current (I)	0.1 – 3 mA	Predicate device: --- Reference device: 0.1 – 3 mA

Maximum RMS stimulation intensity	0.04 mA	Predicate device: --- Reference device: 0.04 mA
Minimum electrode size	0.0097 cm²	Predicate device: --- Reference device: 0.0097 cm²
Maximum current density	4.12 mA/cm²	Predicate device: --- Reference device: 4.12 mA/cm²
Maximum power density	0.93 W/cm²	Predicate device: --- Reference device: 0.93 W/cm²
Maximum charge density	0.41 µC/cm²	Predicate device: --- Reference device: 0.41 µC/cm²
Hardware		
Workstation	Standard personal computer (PC) components	Standard personal computer (PC) components
Printer Capacity	Waveform data can be printed on an external printer	Waveform data can be printed on an external printer
Protection against electrical shock	Class I protection 4000 V	Class I protection 4000 V
Protection against electrical shock of patient leads	Device type BF (Body Floating)	Device type BF (Body Floating)
Housing material	Baydur 110 FR-6	Baydur 110 FR-6
Display unit	White frame, 12-inch display, touch screen buttons	Grey frame, 8.4-inch display, soft-key buttons
PC and storage board	Advantech MIO-3260	Advantech PCM-9361

Summary of Performance Testing:

Biocompatibility: The C2 Xplore does has no patient contact materials, and therefore this section does not apply.

Software: The C2 Xplore contains MAJOR level of concern software. The software was designed and developed according to a rigorous development process, including software verification and validation. Software information is provided in accordance with internal requirements and the following guidance documents and standards:

- FDA guidance: The content of premarket submissions for software contained in medical devices, May 11, 2005
- FDA guidance: Off-the-shelf software use in medical devices, Sep 27, 2019
- FDA guidance: General principles of software validation: Final guidance for industry and FDA staff, Jan 02, 2002
- FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices, Oct 02, 2014

- IEC 62304:2006+A1:2015, Medical device software – Software life cycle processes

Test results demonstrate that the C2 Xplore software complies with its predetermined specifications, the applicable guidance documents and standards.

Electrical Safety:

The C2 Xplore was tested according to the following standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-6:2010 + AMD1:2013, Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-40:2016, Medical electrical equipments – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Test results demonstrate that the products comply with the applicable standards.

Electromagnetic Compatibility:

The essential performance and safety of the C2 Xplore was tested according to the following standards:

- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.

Test results demonstrate that the products comply with the applicable standards

Performance Testing – Bench

The essential performance and safety of C2 Xplore was tested for performance in accordance with internal requirements. The device including their accessories and corresponding intended combinations with further products have been designed according to requirement specifications describing the following aspects:

- General device requirements
- Functional requirements
- External interface requirements
- System accessory requirements
- C2 Xplore software, firmware, and operating system requirements

	The product successfully underwent the bench testing of the requirements at these levels as part of the verification and validation process. Moreover, the testing of the influence of human factors on the device was conducted to demonstrate mitigation of potential use errors and safety of the user interface design. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate.
Performance Testing – Clinical	No additional clinical testing was performed for the C2 Xplore. Therefore, this section does not apply.

Conclusion

In order to establish the performance and safety characteristics, the C2 Xplore underwent successful testing in terms of the device software, electrical safety, electromagnetic compatibility, bench testing, and human factors engineering. The results of these activities demonstrate that the devices are as safe, effective and perform as well as or better than the predicate device.

Therefore, the C2 Xplore including accessories are considered substantially equivalent to the predicate device.