May 5, 2022

MIPM Mammendorfer Institut für Physik und Medizin GmbH
Lukas Spögler
Regulatory Affairs
Oskar-von-Miller Str. 6
Mammendorf, Bavaria 82291
Germany

Re: K212434
Trade/Device Name: Neuromuscular Transmission Monitor TOF3D
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: April 6, 2022
Received: April 11, 2022

Dear Lukas Spögler:

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 and Part 809); 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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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)*
K212434

Device Name
Neuromuscular Transmission Monitor TOF3D

Indications for Use *(Describe)*
The TOF3D is used to objectively monitor the level of neuromuscular transmission by measuring muscle contraction following stimulation. The TOF3D can also be used as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring. The device is intended for use for adolescents greater than 18 through 21 years of age, and adults.

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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5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Permarket 510(k) Summary:

5.1 Submitter Information

Company:	Jennifer Rosenheimer Managing Director MIPM Mammendorfer Institut für Physik und Medizin GmbH Oskar-von-Miller Str. 6 Mammendorf, Bavaria 82291, Germany Telephone: +49 8145 / 92 09 0 Fax: +49 8145 / 92 09 33 quality@mipm.com
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Date Summary Prepared:	April 27, 2022

5.2 Name of the Device

Trade Name:	Neuromuscular Transmission Monitor TOF3D
Common Name:	Neuromuscular Transmission Monitor
Classification Name:	Electrical peripheral nerve stimulator
Review Panel:	Anesthesiology (AN)
Regulation:	868.2775
Class:	Class II
Product Code:	KOI

5.3 Equivalence Claimed to Predicate Device

The Neuromuscular Transmission Monitor TOF3D is equivalent to the TOF-WATCH SX (K992598), manufactured by ORGANON TEKNIKA CORP..

5.4 Device Description

The Neuromuscular Transmission Monitor TOF3D is capable to monitor the level of neuromuscular transmission (NMT) during surgery of in the intensive care unit by stimulating different nerves and measuring the response of the respective muscles to the stimulation. The different locations for monitoring are for instance the ulnar nerve/adductor pollicis muscle, the posterior tibial nerve/flexor halluces brevis muscle and the facial nerve/orbicularis oculi muscle.

The Neuromuscular Transmission Monitor TOF3D uses acceleromyography (AMG) measurement for recording of evoked muscle responses. The results are shown on the LCD display of the device and shall aid qualified medical staff to maintain the proper level of neuromuscular block and to determine the level of recovery from neuromuscular block.

5.5 Indications for Use

The TOF3D is used to objectively monitor the level of neuromuscular transmission by measuring muscle contraction following stimulation. The TOF3D can also be used as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring. The device is intended for use for adolescents greater than 18 through 21 years of age, and adults.

5.6 Substantial Equivalence Discussion

Features	TOF3D (subject device)	TOF-WATCH SX (predicate device)
Stimulation patterns		
TOF	Yes	Yes
PTC	Yes	Yes
1 Hz	Yes	Yes
0.1 Hz	Yes	Yes
DBS	Yes	Yes
TET	Yes	Yes
Nerve location	No	Yes
Maximum simulation voltage	300V (60mA, 5kΩ)	300V (60mA, 5kΩ)
Stimulation current range constant current	0 – 60 mA	0 – 60 mA
Stimulation pulse width	Monophasic, 200 µs or 300 µs	Monophasic, 200 µs or 300 µs
Surface temperature sensor	Yes	Yes

The Neuromuscular Transmission Monitor TOF3D shares the same indications for use, device operation, overall technical and functional capabilities with its predicate device TOF-WATCH SX (K992598). Both devices rely on the use of acceleromyograph to measure muscle response to electrical stimulation to objectively monitor the level of neuromuscular transmission. The additional functionality of the TOF-WATCH SX (nerve location device – localize nerves for loco-regional anesthesia) is based on the same technical principle used for the nerve stimulation functionality, therefore additional risks in clinical application are not to be expected.

The Neuromuscular Transmission Monitor TOF3D is substantially equivalent to the predicate device TOF-WATCH SX (K992598).

5.7 Performance Data

Electrical safety and electromagnetic compatibility (EMC)
The Neuromuscular Transmission Monitor TOF3D complies with the IEC 60601-1, IEC 60601-1-6 and IEC 60601-2-10 standards for safety and performance and the IEC 60601-1-2 standard for EMC-

Software Verification and Validation Testing
The software for this device was considered as a “moderate2 level of concern. Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices”.

Biocompatibility testing
The biocompatibility evaluation for the Neuromuscular Transmission Monitor TOF3D was conducted in accordance with ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”. Based on the results of the biocompatibility evaluation, it can be concluded that the virological safety risks of the TOF3D sensors with accessories are acceptable for use as medical device surface skin contact pars.

Animal and Clinical Studies
No animal or clinical testing was required to demonstrate the substantial equivalence of this device to its predicate.

5.8 Conclusion

The subject device has the same indications for use, technological characteristics, and design and operating principles as the predicate device. The identified differences do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The Neuromuscular Transmission Monitor TOF3D is substantially equivalent to the TOF-WATCH SX, cleared under K992598.