October 21, 2025

MIPM Mammendorfer Institut für Physik und Medizin GmbH
Sebastian Wörl
Regulatory Affairs Supervisor
Oskar-von-Miller Str. 6-7
Mammendorf, Bavaria 82291
Germany

Re: K250887
Trade/Device Name: Neuromuscular Transmission Monitor TOF3D (2510091)
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: September 23, 2025
Received: September 23, 2025

Dear Sebastian Wörl:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250887

Device Name
Neuromuscular Transmission Monitor TOF3D (2510091)

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 TOF3D is intended for use by specialists, anesthetists and nurses with specialization in anesthesia care.

Patients:
The device is intended for use for adolescents greater than 18 through 21 years of age, and adults.

Excluded operating environment:
The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive, flammable and oxygen rich environment or environment with sources of intense electromagnetic disturbances. (e.g. Radio Frequency (RF) shielded room of magnetic resonance imaging equipment, electrophysiology laboratories or areas where short or micro wave therapy equipment is used)

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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K250887

510(k) Summary

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

1.2 Submitter Information

Company:	Jennifer Rosenheimer Managing Director MIPM Mammendorfer Institut für Physik und Medizin GmbH Oskar-von-Miller Str. 6 - 7 Mammendorf, Bavaria 82291, Germany Telephone: +49 8145 / 92 09 0 Fax: +49 8145 / 92 09 33 quality@mipm.com
Contact:	Sebastian Wörl Regulatory Affairs Supervisor MIPM Mammendorfer Institut für Physik und Medizin GmbH Oskar-von-Miller Str. 6 - 7 Mammendorf, Bavaria 82291, Germany Telephone: +49 8145 / 92 09 0 Fax: +49 8145 / 92 09 33 regulatory@mipm.com
Date Summary Prepared:	October 16, 2025

1.3 Name of the Device

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

1.4 Legally Marketed Predicate Devices

Predicate 510(k) number:	K212434
Predicate Trade Name:	TOF3D
Product Code:	KOI

Device Description Summary

The TOF3D is a neuromuscular transmission (NMT) monitor used for objectively monitoring the neuromuscular transmission of patients during surgery or in the intensive care unit. It is intended to be used by specialists, anesthetists and nurses with specialization in anesthesia care. The TOF3D can also be used as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring. The TOF3D is battery powered and uses 4 x 1.5 V AA batteries. The TOF3D has no external power supply.
The neuromuscular transmission is monitored by measuring muscle contraction following stimulation. The TOF3D can perform several different modes of electrical stimulation in accordance with usual clinical practice:

- TOF (Train Of Four)
- PTC (Post Tetanic Count)
- TET (Tetanic Stimulation) 50 Hz or 100 Hz
- DBS (Double Burst Stimulation) (3.2 / 3.3)
- ST (Single Twitch) 0.1 Hz and 1 Hz

The TOF3D uses acceleromyograph (AMG) or mechanomyography (MMG) measurement for recording of evoked muscle responses. By using acceleromyograph (AMG) the acceleration of e.g. the thumb is measured with a three-dimensional acceleration sensor to obtain the muscle force according to the second law of Newton. Different locations for monitoring by using the AMG sensor are for instance the ulnar nerve/adductor pollicis muscle, the posterior tibial nerve/flexor halluces brevis muscle and the facial nerve orbicularis oculi muscle or corrugator supercilii muscle. Mechanomyography (MMG) and the corresponding Mechanomyography sensor (MMG) TOF3D can only be used by stimulating the ulnar nerve and the corresponding measurement of the thumb force with a pressure sensor. All results are shown on the LCD
display of the device.

With the optional temperature sensor or with the integrated temperature sensor in the Mechanomyography sensor (MMG) TOF3D the TOF3D is capable to measure the skin surface temperature (no physiological parameter) during its use.

Based on the force of contraction resulting from stimulation, it is possible to draw conclusions on the level of neuromuscular transmission which shall aid qualified medical staff to maintain the proper level of neuromuscular block and to determine the level of recovery from neuromuscular block.

Intended Use/Indication 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 TOF3D is intended for use by specialists, anesthetists and nurses with specialization in anesthesia care.

Patients:

The device is intended for use for adolescents greater than 18 through 21 years of age, and adults.

Excluded operating environment:

The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive, flammable and oxygen rich environment or environment with sources of intense electromagnetic disturbances. (e.g. Radio Frequency (RF) shielded room of magnetic resonance imaging equipment, electrophysiology laboratories or areas where short or micro wave therapy equipment is used).

Contraindications:

There are no known contraindications to the use of the device.

1.1 Indications for Use Comparison

Indications for Use of the submitted TOF3D device are the same as the ones of the predicate device.

	TOF3D with AMG sensor (Predicate)	**TOF3D with MMG sensor (New)**	**Identified differences or conclusion that there are no differences in characteristic**
Indications for Use/ Intended 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 TOF3D is intended for use by specialists, anesthetists and nurses with specialization in anesthesia care. The device is intended for use for adolescents greater than 18 through 21 years of age, and adults.	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 TOF3D is intended for use by specialists, anesthetists and nurses with specialization in anesthesia care. The device is intended for use for adolescents greater than 18 through 21 years of age, and adults.	Same
Excluded operating environment	The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive, flammable and oxygen rich environment or environment with sources of intense electromagnetic disturbances. (e.g. Radio Frequency (RF) shielded room of magnetic resonance imaging equipment, electrophysiology laboratories or areas where short wave therapy equipment is used).	The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive, flammable and oxygen rich environment or environment with sources of intense electromagnetic disturbances. (e.g. Radio Frequency (RF) shielded room of magnetic resonance imaging equipment, electrophysiology laboratories or areas where short wave therapy equipment is used).	Same
Contraindications	There are no known contraindications to the use of the device	There are no known contraindications to the use of the device	Same

1.2 Technological Comparison

A detailed comparative analysis involving the identified subject and predicate device, has provided sufficient evidence in support of the following conclusion:

The subject device when compared to the predicate device has the same intended use, user profile and patient population, and the same or very similar technological characteristics. Differences in the technological characteristics of the two devices did not raise any new questions of safety and effectiveness, and the resultant test data from the performance tests demonstrated that the subject device is at least as safe and effective as the reference device in terms of the use of MMG in Neuromuscular transmission (NMT) Monitoring applications. There are no significant differences between the TOF3D with its new accessory "MMG Sensor" and the predicate device that would adversely affect the use of the product.

	TOF3D with AMG sensor (Predicate)	**TOF3D with MMG sensor (New)**	**Identified Differences or Conclusion that there are no differences in the characteristic**
Operating principle:	Measuring muscle contraction following stimulation	Measuring muscle contraction following stimulation	Same
Maximum simulation voltage:	300 V (60 mA, 5 kΩ)	300 V (60 mA, 5 kΩ)	Same
Stimulation current range constant current:	0 – 60 mA	0 – 60 mA	Same
Stimulation pulse width:	Monophasic, 200 µs or 300 µs	Monophasic, 200 µs or 300 µs	Same
Stimulation locations:	- Ulnar nerve (adductor pollicis muscle) - Posterior tibial nerve (flexor halluces brevis muscle) - Facial nerve (orbicularis oculi muscle or corrugator supercilii muscle)	- Ulnar nerve (adductor pollicis muscle) - Posterior tibial nerve (flexor halluces brevis muscle) - Facial nerve (orbicularis oculi muscle or corrugator supercilii muscle)	Same
Surface temperature sensor:	Yes	Yes	Same
Stimulation patterns			
TOF	Yes	Yes	Same
PTC	Yes	Yes	Same
1 Hz	Yes	Yes	Same
0.1 Hz	Yes	Yes	Same
DBS	Yes	Yes	Same
TET	Yes	Yes	Same

	AMG sensor TOF3D	MMG sensor TOF3D	Identified differences or conclusion that there are no differences in characteristic
General Operating principle	Measuring muscle contraction following stimulation	Measuring muscle contraction following stimulation	Same
Detailed operating principle	Acceleromyography: Measurement of acceleration and calculation of force according to the second Newton law: F=m.a	Mechanomyography: Direct measurement of force F.	Similar
Stimulation locations	- Ulnar nerve (adductor pollicis muscle) - posterior tibial nerve (flexor halluces brevis muscle) - facial nerve (orbicularis oculi muscle or corrugator supercilii muscle)	- Ulnar nerve (adductor pollicis muscle)	Similar Note: For other locations of stimulation use the AMG sensor
Duration of contact with the human tissues:	A – limited (<= 24h)	A – limited (<= 24h)	Same
Nature of body contact:	Surface – intact skin	Surface – intact skin	Same
TET Mode:	- Stimulation for 5 seconds at 50 or 100 Hz	- Stimulation for 5 seconds at 50 or 100 Hz	Same
Technical Specifications of sensors			
Read-out range	3-254 % (valid data)	3-254 % (valid data)	Same
Read-out resolution within range	1 %	1 %	Same
Invalid Twitch	255 % - If a twitch is invalid [T1] = 255 %; caused by overflow or invalid response.	255 % - If a twitch is invalid [T1] = 255 %; caused by overflow or invalid response.	Same
Accuracy of reading	±5 % of calibrated setting [100 % full scale]	±5 % of calibrated setting [100 % full scale]	Same

Performance Data

1.2.1 Testing Safety

The TOF3D including the MMG sensor is in full compliance with the standards IEC 60601-1 for Basic Safety and Essential Performance and IEC 60601-1-2 for Electromagnetic Compatibility and the device-specific standards IEC 60601-2-10 for basic safety and essential performance nerve and muscle stimulators. All tests have been performed by an independent and accredited testing laboratory.

Test Name	Test Standard	Short Summary of Test Results	Result
Electrical Safety - basic safety and essential performance	IEC 60601-1:2005 +AMD1:2012 +AMD2:2020 (ed3.2)	The TOF3D is a hand-held operated device and is internally powered (batteries). A connection to supply mains is not possible. The performed tests demonstrate robust electrical insulation, effective protection against electric shock, and resistance to environmental stress, ensuring safety and essential performance during normal operation and during single fault conditions. The TOF3D and accessories (incl. MMG sensor) was found to be in compliance with all relevant requirements of IEC 60601-1.	Pass
Electromagnetic Compatibility (EMC)	IEC 60601-1-2:2014 +AMD1:2020 (ed4.1)	The TOF3D is classified as a Class A, Group 1 device according to CISPR 11 emitted radiation and is battery powered only. The TOF3D is intended to be used in professional healthcare facility environment according to the Figure 3 of IEC 60601-1-2. Electromagnetic emissions from the device are well below specified levels in relevant standards and rules as documented in the referenced EMC Test Report. The TOF3D and accessories (incl. MMG sensor) was found to be in compliance with all relevant requirements of IEC 60601-1-2.	Pass
Basic safety and essential performance of nerve and muscle stimulators	IEC 60601-2-10:2012 +AMD1:2016	The TOF3D incl. accessories fulfils the standard specific requirements according to the accuracy of controls and instruments, the protection against hazardous outputs, the usability and the particular EMC requirements. The TOF3D and accessories (incl. MMG sensor) was found to be in compliance with all relevant requirements of IEC 60601-2-10.	Pass

1.2.2 Testing – Labeling / Usability

The usability engineering process of the TOF3D labelling including the application of the MMG sensor to analyse, specify, develop and evaluate the usability of a medical device follows the IEC 60601-1-6 and IEC 62366-1 standards. A description of the MMG sensor as well as its handling, application and specification is included in the Instructions for Use (IFU) of the TOF3D.

Verification has been performed by an independent and accredited testing laboratory.

Test Name	Test Standard	Short Summary of Test Results	Result
Usability	IEC 60601-1-6:2010 +AMD1:2013 +AMD2:2020(ed3.2) In conjunction with IEC 62366-1:2015 +AMD1:2020(ed1.1)	A summative human factors evaluation/usability study of the TOF3D incl. accessories was performed to support the usability of the investigational device. The usability of the medical device as it relates to safety is considered. The usability process of the TOF3D and accessories (incl. MMG sensor) was found to be in compliance with all relevant requirements of IEC 60601-1-6 and IEC 62366-1.	Pass

1.2.3 Testing – Biocompatibility

As the AMG sensor also the MMG sensor comes into direct contact with the patient during its use including the same characteristics (low risk exposure: surface contact, intact skin, limited exposure) as the already approved patient contacting parts. Given the duration of contact and the use on intact skin only, per ISO 10993-1, Annex A, Table A.1, the MMG sensor is also categorized as surface contacting device, with contact duration A – limited exposure (≤ 24h).

Some materials are identical to the materials used in the other patient contacting parts, e.g. the silicone strap adapter is identical to the strap adapter of the approved Hand adapter TOF3D (Ref: 5750101).

The biological safety evaluation of the MMG sensor follows the standard ISO 10993-1.

Test Name	Test Standard	Short Summary of Test Results	Result
Biological Safety Evaluation (Biocompatibility)	ISO 10993-1: 2018 (ed.5)	The applicable biological endpoints which have been considered are physical and/or chemical information, in vitro cytotoxicity, skin sensitization and skin irritation. Based on the risk-based evaluation it can be concluded that the biological safety risks of the patient contacting accessories (incl. MMG sensor) of the TOF3D are acceptable for its intended use (surface intact skin for ≤ 24 h) according to ISO 10993-1.	Pass

1.2.4 Testing – Cleaning/Disinfection, Durability, Transport, etc.

The TOF3D and all its multi-use components and accessories must be cleaned and disinfected in between each patient. Low-level disinfection is generally sufficient. As the AMG sensor also the MMG sensor is reusable and subject to the same cleaning / disinfection procedure. Full verification following the same procedure and acceptance criteria used to support the previously reusable accessories have been performed. The performed cleaning and disinfection tests show, that there is no degradation of basic safety or essential performance, and the device performs as specified, when reprocessed as intended.

1.2.5 Testing – Performance/Functionality

The bench testing to verify the additional MMG sensor TOF3D uses the same method including test setup and equivalent acceptance criteria as with the previously reviewed and approved AMG sensor TOF3D.

Performance testing demonstrates that the TOF3D performs according to its specification outlined in the product and software specifications. The tests address functional, software and performance requirements and does also capture unit-, integration-, functional- and performance tests. The verification included the MMG sensor's dynamic linearity over the entire calibration full scale (FS) force measurement range, measurement repeatability capability with varying input signals, measurement capability with different "excitation points" over the sensor tray surface area and the measurement capability over a measurement period. All requirements have been demonstrated to be fulfilled and the verification proves that all detailed product requirements including accuracy, repeatability and reproducibility are met.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The clinical testing was not required to demonstrate the substantial equivalency of subject device to the predicate device as the technological characteristics of both devices are identical to each other.

Conclusion (Statement of Equivalence)

There are no significant differences between the TOF3D with its new accessory “MMG Sensor” and the predicate device that would adversely affect the use of the product. It is substantially equivalent to the predicate device in design, function, materials, operational principles and intended use.