June 23, 2025

Idmed
Perrine Moelle
Quality & Regulatory Affairs Director
3 rue John Maynard Keynes
Marseille, 13013
France

Re: K243339
Trade/Device Name: WiTOF
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: May 21, 2025
Received: May 21, 2025

Dear Perrine Moelle:

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.

Submission Number *(if known)*

K243339

Device Name

WiTOF

Indications for Use *(Describe)*

The WiTOF is a neuromuscular transmission station (nerve stimulator) that helps to pilot the neuromuscular blockade of adult patients in the operating room, recovery room or intensive care unit.

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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5. 510 (k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

1.1. Submitter

Submitter: IDMED
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13013 Marseille France
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Establishment Registration Number: N° DUNS 260233256

Contact person: Perrine MOLLE
Quality & Regulatory Affairs Director
E-mail : p.molle@idmed.fr

Date Summary Prepared: 2025/06/13

1.2. Device

Trade Name:	WiTOF (reference WiTOF-MU)
Common/Usual Name:	NeuroMuscular Transmission (NMT) station
Regulation Name:	Electrical peripheral nerve stimulator
Classification Regulation:	21 CFR 868.2775
Product Code:	KOI
Regulatory Class:	Class II

1.3. Predicate device

Predicate Device: ToFscan, manufactured by Idmed, K172690

This predicate has not been subject to a design-related recall.

1.4. Device description

The WiTOF is a neuromuscular transmission station (nerve stimulator) that helps to pilot the neuromuscular blockade of adult patients in the operating room, recovery room or intensive care unit. It is used by health professionals (anaesthesiologists, doctors, or fully qualified nurse anaesthetists) for:

1. Objective neuromuscular transmission monitoring
2. Subjective neuromuscular transmission monitoring

The continuous monitoring of NMT blocking involves electrical nerve stimulation and the measurement of acceleration in the corresponding muscle (with a three-dimensional acceleration sensor). Based on the force of contraction resulting from the stimulation, it is possible to draw conclusions about the effectiveness of an injected neuromuscular blocking agents or the patient's curare level.

The device and all of the settings associated with it are designed for use on adult patients in hospital or health institutions so that the patient's curare level can be monitored.

The WiTOF system is composed of the station, the wireless sensor (hand), and the US AC power supply unit. The wireless sensor itself consists of the 3D accelerometer in the splint.

The WiTOF can perform several different modes of electrical stimulation in accordance with usual clinical practice:

- TOF (Train Of Four)
- PTC (Post Tetanic Count)
- ATP (Automated TOF PTC)
- DBS (Double Burst) (3,3) (3,2)
- ST (Single Twitch) 0.1 Hz and 1 Hz
- TET (Tetanus) 50 Hz and 100 Hz

The station displays the various stimulation settings, the time elapsed between stimulations, and the results for the measurements made in response to TOF, PTC, and ATP stimulations. The responses to other types of stimulation are gaged visually by the health professional. The device and stimulation settings are chosen using a display screen.

The accessories that can be used with the device include:

- Optic-serial (RS232) cable to transfer data
- Fixation clamp – regular size (10–40 mm / 0.4–1.6 inches)
- Fixation clamp – large size (20–60 mm / 0.8–2.4 inches)

At a high level, the comparison of the subject and predicate devices is based on the following table:

Features	**WiTOF**	**ToFscan**
Product code	KOI	KOI
Regulation number	868.2775	868.2775
Class	II	II
Indication for use		
Intended use	NMT monitor	NMT monitor

Features	WiTOF	ToFscan
Product code	KOI	KOI
Regulation number	868.2775	868.2775
Class	II	II
Environment of use	Hospital or health institutions: in the operating room, in recovery, or in the intensive care unit	Hospital or health institutions: in the operating room, in recovery, or in the intensive care unit
User	Health professionals	Health professionals
Patient population	Adult patients with neuromuscular blocking agent	Adult and pediatric patients with neuromuscular blocking agent
Contraindication	None known	None known
Principle of operation and performances		
Stimulation Current Output	Constant current, 0-60 mA, monophasic 200µsec pulse width	Constant current, 0-60 mA, monophasic 200µsec pulse width
Maximum stimulation voltage	300V (60 mA, 5kΩ)	300V (60 mA, 5kΩ)
Stimulation		
TOF	Yes	Yes
TOF auto	Yes	Yes
PTC	Yes	Yes
ST 0.1Hz and 1Hz	Yes	Yes
TET 50 Hz	Yes	Yes
TET 100 Hz	Yes	No
DBS 3.3 and 3.2	Yes	Yes
ATP	Yes	Yes
Calculations and measurements		
TOF calculation	Yes	Yes
PTC count	Yes	Yes
T4/T1	Yes	Yes
T4/Tref	Yes	Yes
Displays amplitude of responses / Bars	Yes	Yes
Technological characteristics		
Sensor position	Thumb – accelerometer	Thumb – accelerometer
Type of sensor	Accelerometer	Accelerometer
Type of electrodes	Surface	Surface
Portable device	Yes	Yes
General safety	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10
Connection Data	Wireless connection	Cable connection

1.5. Indications for use

The WiTOF is a neuromuscular transmission station (nerve stimulator) that helps to pilot the neuromuscular blockade of adult patients in the operating room, recovery room or intensive care unit.

The following difference exist between subject and predicate device:

- The subject device is not indicated to be used on pediatric population of patient.

However, this difference does not raise questions of safety and effectiveness, because the population not applicable for the subject device (pediatric) is not taken into account for the comparison. The subject device and its predicate device are both used in the same clinical conditions or purposes (adult patients under anesthesia for whom the effect of neuromuscular blocking agents is monitored) and are used by the same kind of users (Health professional).

1.6. Comparison of technological characteristics with the predicate device

The measuring the muscle movement in response to well-defined electrical nerve stimulation patterns in order to monitor the neuromuscular blocking of a patient is the technological principle for both the subject and predicate devices (acceleromyography).

The following technological differences exist between the subject and predicate device:

- The subject device does perform 100Hz TET stimulation
- The subject device is wireless connected to sensor

However, the differences presented above are supported by performance data (Software verification or safety test reports). Furthermore, these differences do not raise different questions of safety and effectiveness and do not negatively affect the clinical performances for the following reasons:

- Difference of connection to sensor (wireless for subject device): this difference is not clinically significant because the cable-free connection does not influence the results (performance evaluated on the SW verification and validation (see section 1.7 below). Furthermore, the safety of this technology has been tested according to the applicable standards (see section 1.7 below).
- Difference of TET stimulation 100Hz: this performance has been evaluated on the SW verification and validation (see section 1.7 below). Furthermore, this difference is not clinically significant because clinical literatures show that 100Hz stimulation is a common clinical practice used.

1.7. Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biological evaluation for the WiTOF device was conducted in accordance with the FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The thumb splint is the only parts of the WiTOF in contact with the patient: intact skin for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the WiTOF device. The system complies with the IEC 60601-1, IEC 60601-1-6 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

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 Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Animal and Clinical Studies

No animal or clinical testing was required to demonstrate the substantial equivalence of this device to its predicate, nor its safety and effectiveness.

1.8. Conclusions

Based on its intended use, design principles, and technological characteristics, the WiTOF device was found to be as safe, as effective, and performs comparably to the predicate device.

The technological differences identified do not raise new questions of safety and effectiveness as the non-clinical and clinical literature data support the safety of the device and the hardware and software verification and validation demonstrate that the WiTOF device should perform as intended in the specified use conditions.