December 5, 2024

Nerbio Medical Software Platforms, Inc.
% Dave Yungvirt
Accredited Person, Reviewer
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K242525
Trade/Device Name: iTOF
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: November 27, 2024
Received: November 27, 2024

Dear Dave Yungvirt:

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,

James J. Lee -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
iTOF® Wireless Quantitative Neuromuscular Transmission (NMT) Monitor

Trade Name: iTOF

Indications for Use *(Describe)*
The iTOF is a neuromuscular transmission monitor for monitoring the neuromuscular block of a patient in the operating theatre, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510k Summary

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

5.1. Submitter

Nerbio Medical Software Platforms, Inc.
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Kenneth Leonard
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Date Summary Prepared:
24 Aug 2024

5.2. Device

Trade or Proprietary Name:	iTOF®
Common or Usual Name:	Neuromuscular Transmission (NMT) Monitor
Regulation Name:	Electrical peripheral nerve stimulator
Regulation Number:	21 CFR 868.2775
Product Code:	KOI
Class of Device:	Class II
Classification Panel:	Anesthesiology

5.3. Legally marketed device(s) to which equivalence is claimed

510(k)	K172690
Trade/Proprietary Name:	ToFscan
Common Name:	NeuroMuscular Transmission (NMT) monitor
Regulation Name:	Electrical peripheral nerve stimulator

Regulation Number:	21 CFR 868.2775
Product Code:	KOI
Device Class:	Class II
Classification Panel:	Anesthesiology

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

No reference devices were used in this submission.

5.4. Description of the device

The iTOF is an accelerometery based Quantitative Neuromuscular Blockade Monitor that provides continuous, non-invasive neuromuscular transmission (NMT) monitoring by measuring the acceleration of muscle movement (acceleromyography) during controlled electrical stimulations. The iTOF allows medical professionals to accurately monitor and evaluate the depth of neuromuscular blockade of an adult or paediatric patient in the intensive care ward, operating theatre, or recovery room.

It is used by health professionals - anaesthesiologists, doctors, or fully qualified nurse anaesthetists for objective or subjective neuromuscular transmission monitoring.

The iTOF system consists of a mobile device app (User Interface Software), a Bluetooth connected nerve stimulation device (Hardware and Firmware) powered by a 9 Volt non-rechargeable battery, an Accelerometer Sensor, and Stimulation Cables.

The App displays user interface elements including the various stimulation settings controls, the time elapsed between stimulations (all modes), and the results for the measurements made in response to types of stimulation chosen by the user (TOF, PTC, and DBS) (TET and TWI responses are gauged visually by the health professional).

The hardware device portion of the iTOF system provides the electrical stimulation patterns via the Stimulation Cables and quantitatively measures the resulting twitch via the Accelerometer Sensor.

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

- TOF (Train Of Four)

- PTC (Post Tetanic Count)

- DBS (Double Burst) (3.3)

- TWI (Single Twitch) (0.1Hz, 1 Hz, 2Hz)

- TET (Tetanus) (50Hz)

The accessories that can be used with the device include:

- iTOF Splint (included)

5.5. Indications for use

The iTOF is a neuromuscular transmission monitor for monitoring the neuromuscular block of a patient in the operating theatre, recovery room or intensive care unit.

The Indications for Use statement is identical to the predicate device.

5.6 Comparison of technological characteristics with the predicate device

Measuring and/or observing the movement of the thumb in response to well-defined electrical stimulation patterns in order to monitor the neuromuscular blocking of a patient is the technological principle for both the subject and predicate devices.

At a high level, the subject and predicate device are based on the following similar technological elements as presented in the table below.

Stimulation Functions		
Features	**iTOF (subject device)**	**ToFscan (predicate device)**
Stimulation current output	Constant current, 0-70 mA, monophasic 200µsec pulse width	Constant current, 0-60 mA, monophasic 200µsec pulse width
Maximum stimulation voltage	370V (70 mA, 5kΩ)	300V (60 mA, 5kΩ)
Stimulation Mode		
TOF	Yes	Yes
TOF auto	Yes	Yes
PTC	Yes	Yes
0.1Hz, 1Hz, 2Hz ST	Yes	0.1 and 1 Hz only
TET 50 Hz	Yes	Yes
DBS	3.3 DBS only	3.3 and 3.2 DBS
ATP	No (manual selection only)	Yes (automatic and manual selection)

Calculations and Measurements		
Features	**iTOF (subject device)**	**ToFscan (predicate device)**
TOF calculation	Yes	Yes
PTC count	Yes	Yes
T4/T1	Yes	Yes

T4/Tref	Yes	Yes
Displays amplitude of responses / bars	Yes	Yes
Type of sensor	3-D accelerometer	3-D accelerometer
General safety	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEEE/ANSI C63.27	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10

The following technological differences exist between the subject and predicate device:
- The iTOF maximum stimulation voltage and current is 370V (70 mA, 5kΩ)
- The iTOF includes 2Hz ST stimulation
- The iTOF utilizes 3.3 DBS only
- The iTOF allows for manual mode selection only (no ATP)
- The iTOF allows the user to select a repeat frequency interval between 10s to 1h (TOF, ST, DBS) or 30s to 1h (PTC, TET) instead of 15s to 15min only (TOF) or a set duration only (other modes)
- The iTOF utilizes a standard 9V alkaline non-rechargeable battery
- The iTOF utilizes a single accelerometer sensor and separate thumb splint
- The iTOF utilizes a mobile device application user interface through a Bluetooth connection

These differences do not alter the intended diagnostic use of the device nor raise different questions of safety and effectiveness, and are supported by the following performance data.

5.7 Performance data

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

Functional performance testing

Functional performance testing of output waveforms, voltage and current of different stimulation modes and simulated skin resistances.

Biocompatibility testing

The iTOF Splint is a surface-contacting device in direct contact with intact skin for a limited exposure duration of less than 24 hours.

The biocompatibility evaluation for the Splint (part in contact with the patient) which is made up of Latex Free Neoflex™ (thermoplastic elastomer) 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".

- Cytotoxicity
- Sensitization
- Irritation

The Accelerometer Sensor is indirect contact with intact skin for a limited exposure duration of less than 24 hours and the Stimulation Cables are in transient contact with the intact skin of the patient. Both have similarly underdone biocompatibility evaluation 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".

- Cytotoxicity
- Sensitization
- Irritation

Electrical safety and electromagnetic compatibility (EMC)

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

Wireless Coexistence

Due to the wireless functionality of the iTOF, additional wireless coexistence testing was conducted. The system complies with IEEE/ANSI C63.27-2017 Tier 2 & 3, as appropriate for a "moderate" level of concern device under AAMI TIR69 2017 (R2020). The iTOF's wireless technology documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Radio Frequency Wireless Technology in Medical Devices."

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device was considered as a "moderate" level of concern.

Cybersecurity

To ensure safety of the iTOF, effective cybersecurity testing was conducted and management implemented and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

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 (Statement of Equivalence)

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

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

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

There are no significant differences between the iTOF 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.