May 31, 2018

IDMED
Frédéric Bernert
President
Hotel Technoptic
2 rue Marc Donadille
13013 Marseille, France

Re: K172690
Trade/Device Name: ToFscan
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: April 19, 2018
Received: April 19, 2018

Dear Frédéric Bernert:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172690

Device Name

ToFscan

Indications for Use *(Describe)*

The ToFscan is a neuromuscular transmission monitor for monitoring the neuromuscular block of a patient in the operating theatre, recovery room or intensive care unit.
The effect of neuromuscular blocking agents (NMBAs) is monitored by measuring the acceleration of the muscle movement (acceleromyography) or by visually observing muscle contractions consequent to electrical stimulation. The ToFscan has a three-dimensional acceleration sensor (accelerometer) to detect and quantify a patient's thumb movement (contracting adductor pollicis). The sensor is directly integrated into the finger's splint, making it possible to obtain its optimal and reproducible positioning.

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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IDMED
Hotel Technoptic
2 rue Marc Donadille
13013 Marseille – France
☎+33 491 118 784
info@idmed.fr
www.idmed.fr

5. 510 (k) Summary

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

5.1. Submitter

Submitter:	IDMED Hotel Technoptic 2 rue Marc Donadille 13013 Marseille France +33 (0)491 118 784

Establishment Registration Number: N° DUNS 260233256

Contact person:	Frédéric BERNERT President E-mail : f.bernert@idmed.fr
Date Summary Prepared:	2017/12/15
510(k) number:	K172690

5.2. Device

Trade Name:	ToFscan
Common/Usual Name:	NeuroMuscular Transmission (NMT) monitor
Regulation Name:	Electrical peripheral nerve stimulator
Classification Regulation:	21 CFR 868.2775
Product Code:	KOI
Regulatory Class:	Class II

5.3. Predicate device

Predicate Device:	TOF-Watch, manufactured by Organon Teknika, K972698

IDMED
Hotel Technoptic
2 rue Marc Donadille
13013 Marseille – France
☎+33 491 118 784
💻 info@idmed.fr
www.idmed.fr

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

No reference devices were used in this submission.

5.4. Device description

The ToFscan is a neuromuscular transmission (NMT) monitor used for monitoring the neuromuscular block of a patient in the operating theatre, 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 the stimulation of the ulnar nerve and the corresponding measurement of acceleration in the adductor muscle of the thumb (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 apparatus and all of the settings associated with it are designed for use on adult and paediatric patients in hospital or health institutions so that the patient's curare level can be monitored.

The ToFscan system is composed of the monitor, the hand sensor, and the US AC power supply unit. The hand sensor itself consists of the thumb splint/3D accelerometer, the electrode clamps, and the cable which connects to the monitor.

The ToFscan 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

The monitor 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 rotary knob.

The accessories that can be used with the device include:

- Extension Cable 1.9 m
- 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)
- Cable Support

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5.5. Indications for use

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

The effect of neuromuscular blocking agents (NMBAs) is monitored by measuring the acceleration of the muscle movement (acceleromyography) or by visually observing muscle contractions consequent to electrical stimulation. The TOFscan has a three-dimensional acceleration sensor (accelerometer) to detect and quantify a patient's thumb movement (contracting adductor pollicis). The sensor is directly integrated into the finger's splint, making it possible to obtain its optimal and reproducible positioning.

The Indications for use statement for the ToFscan is not identical to the predicate device, however, the differences do not alter the intended diagnostic use of the device nor do they raise different questions of safety and effectiveness of the device relative to the predicate. Both devices rely on the use of acceleromyography to measure muscle response to electrical stimulation as an indication of a patient's curare level. The predicate device has an additional intended use, nerve location, which is not included in the ToFscan.

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 devices are based on the following same technological elements as presented in the table below. The information regarding the nerve location function of the TOF-Watch have not been included as this function is not available on the ToFscan.

Features	**ToFscan (subject device)**	**TOF-watch (predicate device)**
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
0.1Hz and 1Hz ST	Yes	Yes
TET 50 Hz	Yes	Yes
TET 100 Hz	**No**	Yes
3.3 and 3.2 DBS	Yes	Yes
ATP	Yes	**No**
Calculations and measurements		

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Features	ToFscan (subject device)	TOF-watch (predicate device)
TOF calculation	Yes	Yes
PTC count	Yes	Yes
T4/T1	Yes	Yes
T4/Tref	Yes	**No**
Displays amplitude of responses / Bars	Yes	**No**
Type of sensor	Thumb - accelerometer	Thumb - accelerometer
General safety	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10

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

- The ToFscan does not perform 100Hz TET stimulation
- The ToFscan allows the user to select a repeat frequency of TOF stimulation from 15s to 15min instead of 15s only
- The ToFscan includes the ATP mode, a combination of the TOF and PTC stimulation modes
- The ToFscan can measure a patient's reference response to TOF stimulation and calculate T_4/T_{ref}
- The ToFscan monitor displays the amplitude of responses/bars

The differences presented here are supported by following performance data. These differences do not raise different questions of safety and effectiveness.

5.7. Performance data

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

Biocompatibility testing

The biocompatibility evaluation for the ToFscan 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The thumb sensor is the only part of the ToFscan that is in contact with the patient. The ToFscan thumb sensor is a surface-contacting device in contact with intact skin for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

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Electrical safety and EMC testing were conducted on the ToFscan 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.

5.8. Conclusions

Based on its intended use, design principles, and technological characteristics, the ToFscan device was found to be as safe, as effective, and performs comparably to 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 ToFscan device should perform as intended in the specified use conditions.