March 26, 2025

MDE Orvosbiológiai Kutató, Fejleszto,
Aba Tomjanovich
CEO
Gyártó Korlátolt Felelosségu Társaság
Podmaniczky u. 87
Budapest, 1064
Hungary

Re: K240189
Trade/Device Name: NM-01/CPT neurometer (NM-01/CPT)
Regulation Number: 21 CFR 21 CFR 882.1550
Regulation Name: Nerve Conduction Velocity Measurement Device
Regulatory Class: Class II
Product Code: JXE
Dated: February 24, 2025
Received: February 24, 2025

Dear Aba Tomjanovich:

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,

FDA Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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)*

K240189

Device Name

NM-01/CPT neurometer (NM-01/CPT)

Indications for Use *(Describe)*

The NM-01/CPT neurometer is a noninvasive electrodiagnostic device intended for verifying nerve integrity in conscious adult patients, with intact skin surface.

The population of subject for whom this device may be used for diagnostic purposes would include any individual capable of communicating their perception of cutaneous sensation.

The NM-01/CPT neurometer may be conducted as a part of a routine neurological examination. The measured data can be utilized in evaluating patients suspected of having neuropathies. The measured data must be used in the context of other patient information and must be reviewed and interpreted by a physician. The device is intended for use on adults in medical clinics, healthcare practices and out-patient departments of hospitals.

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.

510(k) #: K240189

510(k) Summary

Prepared on: 2025-02-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MDE Orvosbiológiai Kutató, Fejlesztő, Gyártó Korlátolt Felelősségű Társaság
Applicant Address	Podmaniczky u. 87 Budapest 1064 Hungary
Applicant Contact Telephone	+36305968065
Applicant Contact	Mr. Aba Tomjanovich
Applicant Contact Email	qara@mdegmbh.eu

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NM-01/CPT neurometer (NM-01/CPT)
Common Name	Nerve conduction velocity measurement device
Classification Name	Device, Nerve Conduction Velocity Measurement
Regulation Number	882.1550
Product Code(s)	JXE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K843924	Digital Electroneurometer S-100	JXE
K190536	Mediracer	JXE

Device Description Summary

21 CFR 807.92(a)(4)

The NM-01/CPT neurometer is a noninvasive device intended for verifying nerve integrity in conscious adult patients, with intact skin surface. The population of subject for whom this device may be used for diagnostic purposes would include any individual capable of communicating their perception of cutaneous sensation. The NM-01/CPT neurometer may be conducted as a part of a routine neurological examination. The measured data can be utilized in evaluating patients suspected of having neuropathies. The measured data must be used in the context of other patient information and must be reviewed and interpreted by a physician. The device is intended for use on adults in medical clinics, healthcare practices and out-patient departments of hospitals.

The NEUROMETER NM-01/CPT is a unique neurodiagnostic device that painlessly evaluates the functioning of small unmyelinated (C), small myelinated (A) and large myelinated (A) sensory nerve fibers at any cutaneous site by determining neuro selective sensory nerve conduction threshold. The electronic unit emits non-aversive transcutaneous electrical stimuli through a pair of special noninvasive electrodes in three fixed frequency ranges (thick myelin-coated fiber 5Hz, thick myelincoated fiber 250Hz, thin myelin-coated fiber 2000Hz) with a manually adjustable current value. The strength of the emitted stimulus pulses canbe changed between 0.01 and 9.99 mA and their values given by the software are in CPT (Current Precipitation Threshold) values accepted in clinical practice (1CPT = 0.01mA). The test method is sensitive to both hypoesthetic and hyperesthetic abnormalities, and has more than 800 peer reviewed research publications documenting its diagnostic capabilities. The device can measure sensory nerve function at any cutaneous site including mucosal surfaces such as the palate and the bladder and the measures are not affected by skin temperature, edema or electromag-netic interference unlike traditional electro-diagnostic and biopsy procedures. The conducted tests are painless, non-invasive and non-aversive procedure is easy to perform and safe and harmless however it is only for profession clinical use. The evaluation of the tests result could only be approved by a medical doctor but the tests could be conducted by a trained assistant.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The NM-01/CPT neurometer is a noninvasive electrodiagnostic device intended for verifying nerve integrity in conscious adult patients, with intact skin surface.

The population of subject for whom this device may be used for diagnostic purposes would include any individual capable of communicating their perception of cutaneous sensation.

The NM-01/CPT neurometer may be conducted as a part of a routine neurological examination. The measured data can be utilized in evaluating patients suspected of having neuropathies. The measured data must be used in the context of other patient information and must be reviewed and interpreted by a physician. The device is intended for use on adults in medical clinics, healthcare practices and out-patient departments of hospitals.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Neurometer CPT - K843924
"electrodiagnostic devices perform automated neuroselective sensory Nerve Conduction Threshold(sNCT) evaluations by determining Current Perception Threshold (CPT) measures"

NM-01 CPT - K240189
"electrodiagnostic devices perform automated neuroselective sensory Nerve Conduction Threshold (sNCT) evaluations by determining Current Perception Threshold (CPT) measures"

The two devices are substantially equivalent.

Technological Comparison 21 CFR 807.92(a)(6)

The Neurometer CPT (K843924) and NM-01 CPT (K240189) are highly similar in their technological approach. Both are electrodiagnostic devices designed for automated nerve testing and evaluating peripheral neuropathy. They utilize a sinusoidal waveform stimulus and detect nerve responses using verbal and remote-based methods. Additionally, both devices are powered by a rechargeable internal battery, making them portable and convenient for clinical use. Due to these similarities, NM-01 CPT is considered substantially equivalent to the Neurometer CPT.

In contrast, the Mediracer (K190536), while also used for evaluating peripheral neuropathy, employs a different technological approach. Instead of a sinusoidal waveform stimulus, it uses a dual-phase, rectangular waveform.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing was performed on the NM-01/CPT neurometer measurement comparing the measured values with the results of the Neurometer used in clinical practice. For the comparative analysis, we calculated the ratio of the two measurements. We examined the equivalence of the ratios per resistor and per CPT value. For the analysis, we used two-sample TOST tests to check whether the (90%; 111%) interval included the 90% confidence interval of the quotient.

The ratio of the measured result equivalence was above 1 for each resistance (1, 5, 30 Kohm). The confidence intervals do not include a value of 1 in any of the cases, however in all three cases they show a difference within 10% of the confidence intervals (90%; 111%). According to the TOST tests performed the two measurements can be considered within the 10% limit.

For the CPT breakdown, the ratios are above 1 for CPT values between 10 and 250 and below 1 for CPT values above that . The confidence intervals of the ratios for values greater than 10 CPTs are (90%; 111%), and t he TOST tests performed indicate that the two measurements are equivalent within the 10% limit.

For CPT 10, the mean of the ratio is 1.109, with a 90% confidence interval of (1.0531; 1.1648), i.e. in this case the two measurements cannot be considered equivalent within the 10% limit. Note that such values are not expected in the population under study.

To summarise the above, since the measurements were equivalent in all cases except for the 10 CPT values not used in clinical practice, the results of the two instruments can be considered equivalent in the measurement domain to be applied.

Table 1 - Technological Comparison (21 CFR 807.92(a)(6))

	Substantially equivalaent?	**Nerometer CPT - K843924**	**NM-01 CPT - K240189**	**Mediracer - K190536**	**Substantially equivalaent?**
Diseases to be Diagnosed	**Yes**	**Periferal Neuropathy**	**Periferal Neuropathy**	**Periferal Neuropathy**	**Yes**
Intended use	Yes	Performs automated neuroselective sensory Nerve Conduction Threshold (sNCT) evaluations by determining Current Perception Threshold (CPT) measures	Performs automated neuroselective sensory Nerve Conduction Threshold (sNCT) evaluations by determining Current Perception Threshold (CPT) measures	Device for stimulate and measure neuromuscular that are useful in signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.	Yes
Power supply	Yes	Rechargeable Internal Battery	Rechargeable Internal Battery	Rechargeable Internal Batter	Yes
Simulation detection	Yes	Verbal and remote based	Verbal and remote based	Muscle response by electronical measurement	No
Stimulus Type	Yes	Sinusoid	Sinusoid	Dual phase, rectangular wave	No
Resulotion	Yes	0.001 mA	0.001 mA	10 bits	No
Output Current	Yes	0-10 mA Constant AC	0-10 mA Constant AC	NA	No
Stimulation Frequency	Yes	5Hz, 250Hz, 2000Hz	5Hz, 250Hz, 2000Hz	2 Hz	No
Recording Channels	Yes	1 channel	1 channel	1 channel	Yes
Connectivity	No	Wire connection	Bluetooth connection	Bluetooth connection	Yes
Dimensions	Yes	11,43 x 8,89 x 6,35 cm	30 x 12 x 25,5 cm	18.99x6.971	Yes
Electrodes	Yes	Disposable Goldtrode (golden)	Permanent gold coated electrodes	Stimulation Ring Electrode	Yes
Electrode safety	Yes	Cabel chack beofre each usage	automatic sensor displacement detection built in testing protocol for the checking the patient cable damages	NA	No
Controlling the device	Yes	Manual control by buttons of the device	Software based controlling the device that could run on different operating system (Win, Ios, Android)	Software based controlling the device that could run on different operating system (Win)	Yes
Nerves Tested	Yes	small unmylenated (C), small myelinated (Aδ) and large myelinated (Aβ) sensory nerve fibers	small unmylenated (C), small myelinated (Aδ) and large myelinated (Aβ) sensory nerve fibers	Median and ulnar nerves	No
Normative values	Yes	Normative values established for more than 30 multiple testing sites	Normative values included to the software evaluation for more than 30 multiple testing sites	NA	No

Assessment time	Yes	10 - 20 minutes depending on the number of the analyzed arrea	10 - 18 minutes depending on the number of the analyzed arrea	15 minutes	Yes
Access to test data adjustment	Yes	Using the device remote to export the stored measurement values from memory	Cursor placing adjustment	Cursor placing adjustment	Yes
Patient Data Handling and Storage	Neurometer does not have patient handling system.	The device has a built in memory for saving the measured CPT values, data could be saved to a disk for export but it does not have patient management systemvsince it is an analog device	On the software included part of the system. All patient and test data could be stored on the device.	On the software included part of the system. All patient and test data could be stored on the device.	Yes
Operator Skill Requirements	Yes	Trained technician supervised by a physician or a physician	Trained technician supervised by a physician or a physician	Trained technician supervised by a physician or a physician	Yes
Interpretation of the Test Results	Yes	Physician or specialist locally	Physician or specialist locally	Physician or specialist locally	Yes
Examination areas	Yes	Examination of all skin/mucous membrane areas	Examination of all skin areas	forarm and foot	Yes
Alternative measurement protocols	Yes	Suitable to measure a patient's Pain Tolerance Threshold (PTT)	Suitable to measure a patient's Pain Tolerance Threshold (PTT)	NA	No
Regulations	NM CPT is under FDA Approval	FDA and CE mark	CE - marked	FDA and CE mark	Yes