Mediracer Oy
Lassi Laitinen
Product Specialist R&D
Rantakatu 4
Oulu, 90100 FI

Re: K190536
Trade/Device Name: Mediracer NCS
Regulation Number: 21 CFR 882.1550
Regulation Name: Nerve Conduction Velocity Measurement Device
Regulatory Class: Class II
Product Code: JXE
Dated: August 26, 2019
Received: August 30, 2019

Dear Lassi Laitinen:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190536

Device Name
Mediracer NCS

Indications for Use *(Describe)*
The Mediracer NCS is intended to measure sensory and motor nerve conduction from peripheral nerves. The measured data can be utilized in evaluating patients suspected of having focal neuropathies. The measured data must be used in the context of other patient information and must be reviewed and interpreted by a physician.

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.

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510(K) SUMMARY

Submission type:	Traditional 510(k)
Basis for submission:	New device introduced

Submitter information

Sponsor:	Mediracer Oy (Ltd.)
Address:	Rantakatu 4
	90100 Oulu
	Finland
Contact person:	Georg Meissner, CEO
Phone:	+358 40 517 0182
Submission date:	19/09/2019

Device information

Trade name:	Mediracer NCS
Common name:	Nerve Conduction Testing System
Classification name:	Nerve Conduction Study Measuring
Device Class:	Device Class II (21 CFR 882.1550)
Product Code:	JXE

Predicate device

NeuroMetrix ADVANCE	K070109

1 DEVICE DESCRIPTION

The Mediracer NCS is intended to measure sensory and motor nerve conduction from peripheral nerves, when there is reason to suspect nerve damage. The measured data can be utilized in evaluating patients suspected of having focal neuropathies. Current application allows examination of Carpal Tunnel Syndrome related median nerve entrapment and ulnar nerve entrapment at the elbow. Test results can be used to determine if the findings are abnormal and in CTS, grade the severity of the nerve entrapment.

The Mediracer NCS is a hand-held NCS Device to stimulate and record the nerve responses from patient. The NCS Device is connected to the disposable surface electrodes with cables provided with the NCS Device. The NCS Device communicates via Bluetooth with a computer which is using The Mediracer Analysis Center (MAC) software. The computer

uses the MAC software to store and handle the patient measurement data. With the NCS Device comes a charger and a docking station for charging the NCS Device. Also, solution includes a test module for checking the functionality of the whole test system.

Mediracer NCS is used by physician or by technician on the order of physician for measuring sensory or motor nerve conductions from distal nerves. The measured data is transferred during the measurement to a computer via Bluetooth connection. The data measured is reviewed and interpreted by a specially trained physician or specialist in neurophysiology.

2 INTENDED USE

The Mediracer NCS is intended to measure sensory and motor nerve conduction from peripheral nerves. The measured data can be utilized in evaluating patients suspected of having focal neuropathies. The measured data must be used in the context of other patient information and must be reviewed and interpreted by a physician.

3 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Mediracer NCS which is the subject of this Premarket Notification is substantially equivalent in sensory nerve conduction studies to the predicate device, NeuroMetrix ADVANCE. All the other functions of the predicate device are ignored in the comparison. Neuromuscular signal measurement is the technological principle for both the subject and predicate devices. It is based on stimulating the nerve with electric stimulus on skin above the nerve and the activated nerve response is measured on skin from the same nerve at some distance of the stimulus.

Difference between the devices are mainly in the design and the technological specifications due to the design. None of the different features of Mediracer NCS compared to predicate device have altered the basic performance, operation or intended use. At high level, the subject and predicate devices are based on the following same technological elements:

- stimulating and recording electrodes
- stimulation and recording cables
- hand-held, point-of-care, device that performs the measurement
- Bluetooth for data transfer

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

- Electrodes differ in design and placement.
- The cables differ in design, the predicate uses the Proximal adapter in which the stimulation cable and recording cable are connected whereas the subject device has two separate cables which are connected straight to the device.
- Hand-held device differs from the display of data, the predicate uses touch screen for display of data whereas the subject device uses small LCD screen.
- The subject device must be used in conjunction with the Mediracer Analysis Center (MAC) whereas predicate device can be used without any external software.

Table 1. Device Comparison

	Advance NCS	**Mediracer NCS**
Intended use	Device for measuring neuromuscular signals that are useful as an aid in diagnosing and evaluating patients suspected of having focal or systemic neuropathies.	Device for stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.
Power supply	High Capacity Lithium Ion Battery	Battery: Nickel Metal Hybrid NiHM battery 6V, 730 mAh
Common Mode Rejection Ratio	90 dB min	95…100 dB at 1 kHz
Noise	<2μV RMS	1.0 μV RMS (from 2 Hz to 10 kHz)
Sampling Frequency	20 kHz	14.6 kHz
A/D Resolution	24 bits	10 bits
Stimulus Type	Monophasic or biphasic square wave	Dual phase, rectangular wave
Stimulator Max Voltage	420 V	163 V
Stimulation Frequency	2 Hz	2 Hz
Recording Channels	1	1
Connectivity	Bluetooth	Bluetooth
Latencies	Motor and sensory latencies	Motor and sensory latencies
Dimensions	18.034 x 8.128 cm	18.99 x 6.971 cm
Nerves Tested	Median and ulnar nerves	Median and ulnar nerves
Test Signal Control During Test	Automatic or manual adjustment depending on the used electrodes	Manual adjustment
Assessment time	10 minutes	15 minutes (both hands)
Access to test data adjustment	Cursor placing adjustment	Cursor placing adjustment
Electrodes	Nerve specific wrist and digit electrodes or standard electrodes (also elbow and foot electrodes available)	Stimulation Ring Electrode and Recording Electrode
Patient Data Handling and Storage	On the Device. All patient and test data included. Can be uploaded to a Data Server.	On the software included on the system. All patient and test data included.
Operator Skill Requirements	Trained technician supervised by a physician or a physician	Trained technician supervised by a physician or a physician

Interpretation of the Test Results	Physician or specialist locally	Physician or specialist locally or remotely
Temperature	Temperature sensor integrated	Temperature measurement with a separate device
Regulations	CE -Marked; 60601-1 compliance	CE -Marked; 60601-1 compliance

4 PERFORMANCE DATA

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

Biocompatibility testing

The Mediracer NCS component relevant for biocompatibility evaluation is the Electrode conductive hydrogel, which is in direct contact of patient skin while conducting the NCS test. Conductive hydrogel was assessed according to International Organization of Standardization 10993-1: *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*.

Performance Testing includes the biocompatibility test, bench test and clinical tests. Detailed descriptions of the biocompatibility test, bench test and clinical tests are included in the submission. The testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization

The hydrogel passed all above ISO 10993 testing.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Mediracer NCS device, consisting of the NCS device (ENG-CC-02), patient stimulator (PS-01), stimulation cable (SC-01) and recording cable (CC-02). The system complies with the IEC 60601-1, IEC 60601-2-40 standards for safety and the EN 60601-1-2[1] standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing for the Mediracer NCS and MAC, were conducted, and documentation was provided as recommended by FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software of Mediracer NCS device and the MAC software was considered "Moderate" level of concern, since there is a risk of minor adverse events associated with Mediracer NCS and the MAC software is an accessory to a Medical Device (Mediracer NCS).

[1] The European version (60601-1-2:2015) of the standard and the IEC-version (60601-1-2:2014) are equivalent to each other. In the European version the differences to its IEC counterpart are the exception of references of the 61000-4-x series and the addition of an Essential Requirements annex. The technical content of the IEC version is identical to the EN version.

Performance testing

Performance testing as a bench-testing, was conducted to the subject device to show equivalence to a previously approved device and to verify Mediracer NCS device accuracy. The performed test was same for both devices and the testing was performed by a trained operator.

The testing was performed to seven people, which six was within the measurement criteria set before testing. The six results taken into account with proper placement show significantly similar nerve response action potential values. The results show that the Mediracer NCS device results compared to conventional EMG device were matching inside the given deviation. Based on this comparison test it can be said that Mediracer NCS device is equivalent to a conventional EMG device and shows accurate readings.

Clinical Studies

The clinical validation was made against traditional nerve conduction test devices in two separate studies; one in Finland and the other in the United Kingdom. All the subjects examined in these tests had AANEM 2002 recommended set of traditional nerve conduction studies (NCS) and measurement with the Mediracer NCS done.

In the Finnish multicenter study, there were 194 recruited patients and 95 healthy control volunteers tested. The participants went through a clinical examination, Mediracer NCS measurement and the traditional NCS. In the United Kingdom study, the devices were compared only in the patient population, total of 63 patients participated in the study. The participants went through clinical assessment, Mediracer NCS measurement and the traditional NCS.

In the Finnish multicenter study, the number of patients studied were 194, aged 17-85, mean 49 years. Of these patients 147 (75.77 %) were female. Exclusion criteria for the study were prior surgery for CTS (the measured hand), neurological disorder that may produce numbness or paraesthesias in hand and those with diagnosed diabetes mellitus. For the study control values of 95 healthy volunteers aged from 16-80, mean 41 years, were examined. Of these volunteers 52 (54.73 %) were female. In the United Kingdom the patients were recruited from the normal referral stream to Leicester Carpal Tunnel Service, total of 104 referrals were selected and invited to a clinical study. No other exclusion criteria. Of the invited patients 65 fulfilled the clinical CTS diagnosis after symptom inquiry and clinical assessment. On the day of the study two participants cancelled their involvement, thus the total participation number were 63 patients. Of these patients 47 (74.60 %) were female.

Safety and effectiveness

In both studies positive per cent agreement between the traditional and the Mediracer NCS devices was around 90 % and negative per cent agreement 99-100 %. The new device study missed abnormalities mainly in cases with very mild conduction slowing and due to technical (one broken cable) or biological causes (patient was unable to relax). A high concordance between the used latency difference parameters between the traditional and the new device study were obtained. Moreover, these parameters were not dependent on skin temperature as absolute conduction velocities clearly are. The method is non-invasive and is safe to preform for the patients, no adverse effects or complications were reported during these studies.

Summary

Based on the two studies performed, the Mediracer NCS measurement device seems to reliably detect the median nerve lesion in CTS. In the studies were found high degree of agreement between the systems compared, the new and traditional methods of NCS testing.

5 CONCLUSIONS

The non-clinical data support the safety of the device and the Mediracer NCS and MAC software verification and validation demonstrate that the Mediracer NCS device should perform as intended in the normal use conditions. The clinical data and bench-testing demonstrates that nerve conduction measurements obtained using the Mediracer NCS are comparable to those obtained using conventional nerve conduction measurement equipment.