JUL 2 3 2014

K141208

Section 5

510(K) Summary

5.1 Submission Correspondent and Owner

Submission Correspondent

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Sponsor (Owner)

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email: jbernhard@prosenex.com

5.2 Date Summary Prepared

May 2, 2014

5.3 Device Trade Name

Dynamic Neuroscreening Device

5.4 Device common name

Temperature Discrimination Device and Tuning Fork

5.5 Device classification name

Temperature Discrimination Test, LQW, Unclassified

5.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

The Dynamic Neuroscreening Device is substantially equivalent to:

- The Sensortek NTE-2 Thermal Sensory Tester cleared under K864345.
- The Somedic Vibrameter cleared under K843486.

5.7 Description Of The Device

The Dynamic Neuroscreening Device (DND) is intended to screen patients and allow the practitioner to observe any changes of sensation over a period of time. The device will be available with a cradle which provides a docking location for the handle. The DND device provides medical practitioners with an objective method for screening patient's feet for neuropathy. The device uses two methods for long term screening with the objective of determining loss of sensation in the patient's foot: vibration sensitivity and temperature discrimination screening. The primary patient population is for those that are at risk or have been diagnosed with diabetes.

The DND is designed to be ergonomically comfortable in the practitioner's hand and simple to use. In addition safety features are installed to prevent the device from becoming excessively hot or cold to ensure patient safety. No electrical pathways are going to the patient and the power supply is UL approved to the medical device standard.

5.8 Intended Use

The Dynamic Neuroscreening Device (DND) is intended to provide objective medical screening for peripheral neuropathy by determining the patient's ability to discriminate temperature differences as well as determining vibration sensitivity.

5.9 Technological Characteristics

The Dynamic Neuroscreening Device has identical technical characteristics as the predicate devices. Table 5.1 describes the basic features of the DND as compared to the Sensortek NTE-2 Thermal Sensory Tester cleared under K864345 and the Somedic Vibrameter cleared under K843486. Comparisons related to temperature and vibration are presented.

Table 5.1: Technological Characteristics Comparison Table

Feature or Specification	Sensortek NTE-2 Thermal Sensory Tester (K864345)	Dynamic Neuroscreening Device (Proposed Device)
Minimum Temperature (deg C)	0	15
Maximum Temperature (deg C)	50	40
Control Accuracy (deg C)	0.1	0.5
Temperature Gradient Steps (deg C)	5, 1, and 0.5	Fixed at 2

Feature or Specification	Somedic Vibrameter (K843486)	Dynamic Neuroscreening Device (Proposed Device)
Vibration Frequency (Hz)	100-120	175
Vibration Amplitude Range (microns)	0 to 40 and 0 to 400	4.5 to 23
Vibration Amplitude Set Point Resolution (Microns)	5%	20%

5.10 Non-Clinical Testing

Nonclinical testing consisted of vibrational and temperature verification in addition to electrical safety testing.

5.11 Biocompatibilty

Due to the materials of construction, biocompatibilty testing was not performed.

5.12 Clinical Testing

No clinical testing was performed in association with this submission.

5.13 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2014

Prosenex, LLC
C/O Bill McLain
Principal Consultant
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, PA 17540

Re: K141208
Trade/Device Name: Dynamic Neuroscreening Device
Regulation Number: Unclassified
Regulation Name: Temperature Discrimination Test
Regulatory Class: Unclassified
Product Code: LQW and LLN
Dated: May 2, 2014
Received: May 9, 2014

Dear Mr. McLain:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine 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)*

K141208

Device Name

Dynamic Neuroscreening Device

Indications for Use *(Describe)*

The Dynamic Neuroscreening Device (DND) is intended to provide objective medical screening for peripheral neuropathy by determining the patient's ability to discriminate temperature differences as well as determining vibration sensitivity.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S

Date: 2014.07.23 21:16:49 -04'00'

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