

MAY 20 1998

**510 (k) SUMMARY
807.92**

K980866

Submitted: James L. Hedgecock, DC, PhD
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Contact person: Dr. James L. Hedgecock
Date Submitted: 11/06/97
Name of Device: Medi-Dx 7000 510 (k) 964622
Equivalent Device: Neurometer by Neurotron; 510(k) 853608

This Summary is the same as the previously accepted one with the exception of the inclusion of the AMREX electrodes mentioned in the GENERAL COMPARISON (below).

GENERAL DESCRIPTION OF THE MEDI-DX 7000:

Approved 12/01/97, the Medi-Dx 7000 is a Current Perception Threshold (CPT) device for the examination of peripheral neuropathies. It generates sinusoidal electrical currents in the 5 Hz, 250 Hz and 2000 Hz frequencies from 0 mA to 9.99 mA.

The Medi-Dx 7000 weighs approximately 15 lbs. and is housed within a 12" x 5" x 11" heavy duty plastic case with metal face and rear panels. The rear panel has an access door for installation and replacement of (8) standard (6) Volt Alkaline Batteries. The Face panel has an 'ON/OFF' switch, a 'Battery Test' switch (also functioning as an automatic calibration switch), and three (3) switches, one for each of the frequencies; 5 Hz, 250 Hz and 2000 Hz respectively. The intensity control is immediately below an LCD which reads mA output. Two ports are available on the front panel for connection with electrodes.

INDICATIONS AND USAGE:

The Medi-Dx 7000 is a diagnostic device for the quantitative detection of sensory neurological impairments. The population of subjects for whom this device may be used for diagnostic purposes would include any individual capable of communicating their perception of cutaneous sensation.

The Medi-Dx 7000 diagnostic examination may be conducted as part of a routine neurological examination or as a screening procedure for the detection of peripheral neuropathy which may be caused by various pathological conditions or exposures to toxic substances.

GENERAL COMPARISON:

The Medi-Dx 7000 and the equivalent (Neurometer) device are essentially the same, they weigh and have approximately the same size. Both have the same minimum / maximum output (0.0 mA to 9.99 mA). The same current characteristic (sinusoidal waveform) and the same frequencies (5 Hz, 250 Hz and 2000Hz). The Medi-Dx 7000 can be used with the electrodes of the equivalent device or with electrodes distributed by AMREX. The AMREX system is made up of a large general ground electrode and a small single electrode. The Medi-Dx 7000 is shipped with whichever electrodes the purchaser has chosen.

TECHNICAL DIFFERENCES:

- 1) The Medi-Dx 7000 does not have a built in battery charger, as does the equivalent device (Neurometer), which is powered by NiCd rechargeable batteries with a built in recharger.
- 2) The Medi-Dx 7000 is fully manually controlled and the Neurometer has a manual and an auto-test mode.
- 3) The Medi-Dx 7000 uses the voltage as-is without stepping up, so the maximum available voltage is +5 v to -5 v to operate the internal circuitry. The equivalent device has a step up of 10 times with an internal switching power supply, so the maximum voltage is +85 v to -85 v to operate the internal circuitry.

Continued:

- 4) The Medi-Dx 7000 has an isolated output via the transformer. No transformer isolation of output is used in the equivalent device, which depends on non-failure of the charger and selector switch to prevent 110v AC leakage.
- 5) The Medi-Dx 7000 case is largely non-conducting plastic, whereas the equivalent device has an all metal case.
- 6) No-load conditions will not build up an electrical field at the electrodes, because the output is dampened. It is not known if the equivalent device has such output dampening.
- 7) Four independent clocks for frequency production are used in the Medi-Dx 7000 device. The equivalent device uses one master clock which is Crystal controlled. The result is that the equivalent device produces RFI and the Medi-Dx 7000 does not.
- 8) The Medi-Dx 7000 has a safety interlock which disconnects the power supply if the case is opened.
- 9) The Medi-Dx 7000 has a digital LCD output meter and the equivalent device does not.

SIMILARITIES:

The following technical similarities are noted:

- 1) The Medi-Dx 7000 "WARNING" light flashes if the power drops below that needed to supply the maximum output of 9.99 mA. The equivalent device has a "WARNING" light that is "steady on" to warn of low batteries. This same light is used to warn of clipping of the waveform. In the case of clipping, the Warning light will flash when the intensity is increased, whereas the warning light will flash at 0 (zero) when the battery is low.
- 2) Neither device poses any environmental risk from chemical, thermal, radiation or mechanical factors.
- 3) Both devices deliver current to the subject that is biologically compatible and poses no threat of injury to the patient or operator.
- 4) Both use an LCD readout of current.
- 5) Both use a master power switch.
- 6) The Medi-Dx 7000 uses separate switches to isolate each frequency and two switches cannot be turned on at the same time. The equivalent device uses a selector knob to isolate the frequencies.
- 7) Both use a digital waveform filter to produce an analog output.
- 8) Both manufacturers "burn in" the devices for 168 hours and testing insures accuracy/calibration.

Tests and trials:

Since the current output, waveform are the same, it is reasonable to assume that the two devices are the same in function and reliability.

It will be noted that almost all the differences relate to improved safety of the Medi-Dx 7000 as compared to the equivalent device. The only difference in operation is that the Medi-Dx 7000 does not use an auto-test mode, which is employed in the equivalent device. This auto-test mode is employed in such a way that the subject is purposely stimulated above the threshold and then below in such a fashion as to "home in" on the threshold. However, it is the contention of the Medi-Dx 7000 manufacturer and the opinion of neurologists and other medical experts the manufacturer has consulted with, that this practice can in practice actually alter the threshold by "over stimulating" the receptors and any supposed advantage in accuracy by testing in this auto-test mode is outweighed by the fact that this auto-test mode may be slightly increasing the current required to produce a threshold stimulation. In other words the over stimulation of the receptors causes receptor fatigue and more receptors, i.e. more current, is required to reach a threshold stimulation with each stimulation above the threshold. Several of these physicians have compared the devices clinically and have agreed to share their opinions if contacted. Their names and phone numbers will be supplied upon request.

Sincerely,



James L. Hedgecock



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

James L. Hedgecock, Ph.D.
•Neuro-Diagnostic Associates
445 Dartmoor Street
Laguna Beach, California 92651

Re: K980866
Trade Name: Medi-Dx 7000 with AMREX Electrodes
Regulatory Class: II
Product Code: GWF
Dated: February 17, 1998
Received: February 19, 1998

Dear Dr. Hedgecock:

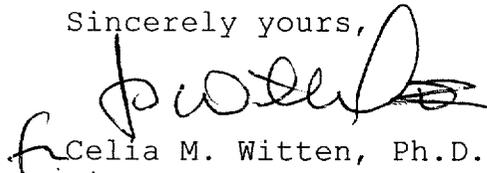
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE:

(k) 980866

DEVICE NAME: MEDI-DX 7000 with AMREX ELECTRODE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980866

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)