Section E: 510(k) Summary

Submitted by: Medical Technologies Unlimited, Inc.
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Date Prepared: June 20, 2003
Contact Name: Marco Vitiello, M.D.
Product Trade Name: Comprehensive Neuromuscular Profiler
Classification Name: Diagnostic Eletromyograph (890.1375)

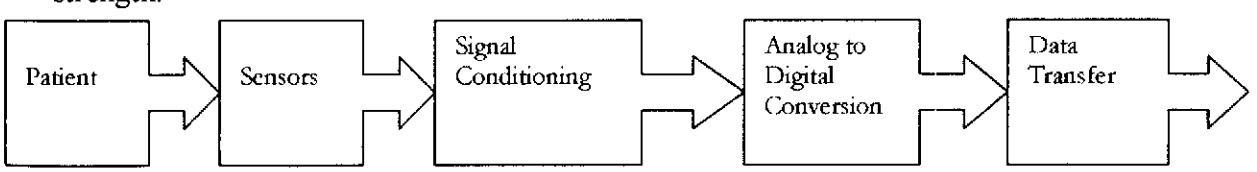
List of Predicate Devices to which we claim substantial equivalence

1. Physical Monitoring Registration Unit (K022719)
2. Combined Physiological Monitoring System (K002104)

Description of Device

The Comprehensive Neuromuscular Profiler is a muscle and range of motion monitoring system that is portable, stand-alone and in a convenient package suitable for use in a medical environment. The system consists of a number of sensors to be connected to various parts of the human body which will be fed into a customized enclosure containing all connectors and mediums for conditioning, acquiring and transferring the sensor data. The conditioned data will then be sent to the notebook computer (PC) that is connected to the enclosure.

The system will be capable of monitoring and recording data from electromyography (EMG) sensors connected to various muscle groups in the human body. During the acquisition of EMG signals, the system will simultaneously acquire motion of the body and/or muscle strength.



Intended Use of Device

The CNMPs primary intended use is for muscular injury testing. It strives to achieve this goal through non-invasive testing, using range-of-motion and functional capacity integration, as well as using standard EMG sensors. The CNMP is specifically designed to testing the cervical, thoracic and the upper and lower extremities. It observes muscle functioning and characteristics. These functions and characteristics include muscle tone, fatigue, and a number of activities which take place in the muscle. The CNMP can be used in a number of arenas, such as sports medicine, rehabilitation clinics, employee evaluation, and litigation.

Summary of Technological Characteristics of Device Compared to Predicate Device

The CNMP and the predicate systems both use a range of motion device in combination with functional capacity devices and EMG sensors to obtain similar data. Like the predicate systems, the CNMP uses an off-the-shelf grip strength sensor and an off-the-shelf, standard load cell-based pinch strength sensor. The off-the-shelf ROM device used by the CNMP allows a more accurate method of data acquisition, and it provides more freedom for the patient. The EMG system used by the CNMP covers a greater frequency range and allows for a more substantial amount of signal filtering and conditioning through noise reduction and increased resolution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2004

Medical Technologies Unlimited, Inc.
c/o Ms. Angela Morris
ALM Consulting
7538 Bear Canyon Road, NE
Albuquerque, New Mexico 87109

Re: K031995
Trade/Device Name: Comprehensive Neuromuscular Profiler
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: IKN
Dated: October 8, 2003
Received: October 9, 2003

Dear Ms. Morris:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milham

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

Enclosure

Indications for Use

510(k) Number (if known): K031995

Device Name: Comprehensive Neuromuscular Profiler

Indications For Use:

Surface electromyography with range of motion tracking, functional capacity and pinch and grip strength measuring.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031995