Advantage
Medical
A Division of CME Telemetrix

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K973355

DEC - 5 1997

510(k) SUMMARY

Date:
September 4, 1997

Submitter's Name and Address:
Advantage Medical
A Division of CME Telemetrix
100 - 100 Collip Circle
London, ON Canada N6G 4X8

Contact Name:
Mr. Robert Snow
Advantage Medical
A Division of CME Telemetrix
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London, ON Canada N6G 4X8

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K 973355

Trade Name:	ADVANTAGE 3000
Common Name:	EMG/EP System
Classification Name:	Diagnostic Electromyography / Evoked Response Electrical Stimulation System
Substantially Equivalent to:	Advantage EMG/EP System K885246
Classification:	Class II, 21 C.F.R. §890.1375 & §882.1870
Intended use:	The Advantage 3000 system diagnoses disorders of the nervous and muscular systems.
Technological characteristics:	Using surface electrodes, signals are recorded from the surface of the skin or directly from the nerves or muscles by means of needle electrodes. It is also possible to provide a timed stimulus to the patient, so that the response to the stimulus can be recorded and analysed. The signals from the subject are taken through the headbox to the control module and the computer for display and analysis. The computer is based on the Intel Pentium architecture. Differences from the predicate device are the inclusion of a constant voltage stimulator, a more efficient operating interface, a reduction in the wattage of the speaker, the availability of a portable system, and the size reduction of the laboratory based system. Beyond these differences both devices have the same technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Snow
Advantage Medical
Division of CME Telemetrix
100 Collip Circle #100
London Ontario
N6G 4X8
CANADA

DEC - 5 1997

Re: K973355
Trade Name: Advantage 3000
Regulatory Class: II
Product Code: IKN
Dated: September 4, 1997
Received: September 8, 1997

Dear Mr. Snow:

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.

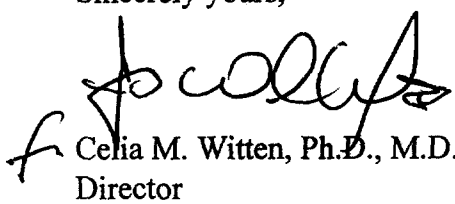
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , 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

510(k) Number: K973355

Device Name: Advantage 3000

Indications for use:

The Advantage 3000 is a Diagnostic Electromyography/Evoked Response Electrical Stimulation (EMG/EP) System designed for the monitoring and analysis of electromyography data. A variety of electrophysiologic tests can be performed to determine whether disease of peripheral nerves or muscles is present in adult and pediatric patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973355

Prescription Use ✓ or Over-The-Counter Use ____