

K 974010

**II. 510(k) SUMMARY**

JAN 16 1998

Date: October 16, 1997

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

Contact Person: Robert Snow  
General Manager  
Advantage Medical  
A Division of CME Telemetry, Inc.  
100 - 100 Collip Circle  
London, ON Canada N6G 4X8

Tel # 519-858-5011  
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Trade Name: Advantage EMG System, Model #A100

Common Name: EMG System

Classification Name: Diagnostic Electromyograph

Substantial Equivalent Device: Advantage EMG System, Model #A100 (K885246)

Classification: Class II, 21 C.F.R. § 890.1375

Intended Use: The Advantage EMG System, Model #A100 is a Diagnostic Electromyography (EMG)/Evoked Response Electrical Stimulation System for the diagnosis of nervous and muscular system disorders in adult and pediatric patients.

Technological Characteristics: The technological characteristics remain unchanged as a result of the modification to the device. 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 analyzed.

The signals from the subject are taken through the headbox to the control modules and the computer for display and analysis. The computer is based on the Intel XX086 architecture.

The only modification made to the device is the removal of diodes contained in the pre-amplifier circuitry.

**Testing to Support  
Substantial Equivalence:**

To provide support that the proposed corrective modification would be effective, and would not adversely affect the device, a failure investigation, along with electrostatic discharge and actual use testing were conducted consistent with 21 C.F.R. §§820.100 (corrective and preventive action) and 820.198(d) (failure investigations). The analyses and testing confirmed that the proposed corrective action is effective, and that it did not affect the safety or effectiveness of the product.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Robert Snow  
General Manager  
Advantage Medical  
The Research Park, University of Western Ontario  
#100 - 100 Collip Circle  
London, Ontario N6G 4X8  
Canada

JAN 16 1998

Re: K974010  
Trade Name: Advantage EMG System, Model #A100  
Regulatory Class: II  
Product Code: IKN  
Dated: October 20, 1997  
Received: October 21, 1997

Dear Mr. Snow:

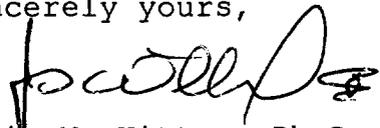
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

  
f. 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 974010

**510(k) Number:**

K885246

**Device Name:**

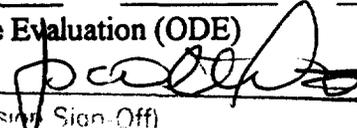
Advantage EMG System, Model #A100

**Indications for Use:**

The Advantage EMG System, Model #A100 is a Diagnostic Electromyography (EMG)/Evoked Response Electrical Stimulation System for the diagnosis of nervous and muscular system disorders in adult and pediatric patients.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General Restorative Devices

510(k) number

K974010

Prescription Use

or

Over-The-Counter Use