APR 1 8 2000

K000865

II. 510(k) SUMMARY

Submitted by: Neurosoft, Inc
45150 Business Court, Suite 100
Sterling, VA 20166

Contact Person: David B. Jones
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Date Prepared: March 17, 2000

Proprietary Name: Quik-Cap EEG Electrode Positioning System

Common Name: Electrode Positioning Cap

Classification Name: Electrode, Metallic with Soft Pad Covering (84IKS)

Predicate Device: Electro-Cap VII System
510(k) #K780045

Description of the Device: The Quik-Cap is a system for rapidly positioning large numbers of electroencephalograph (EEG) electrodes on the head. The Quik-Cap consists of a stretchable fabric cap, metal disk electrodes, electrode holders, and electrode lead wires. The electrode holders are made of soft rubber and the wires are maintained on the outside of the cap.

Intended Use of the Device: The Quik-Cap has the same intended use as the predicate electrode cap and is intended for routine clinical settings where rapid placement of large numbers of EEG electrodes is desired.

Technological Characteristics: The previously established electrode application techniques required that an experienced technician measure the head of a patient to determine the electrode positions in accordance with the International Ten-Twenty System (10-20) of Electrode Placements.[1] After manually locating the 10-20 positions on a patient's head, the technician would then attach each electrode using collodion and a conductive paste. This process is very time consuming and uncomfortable for the patient. The predicate device, a cap-style multi-electrode electrode placement device, assists EEG technicians by attaching

[1] Ten Twenty Electrode System, International Federation of Societies for Electroencephalography and Clinical Neurophysiology. EEG Clinical Neurophysiology, 10: 371-375, 1958.

and fitting large numbers of electrodes on the head simultaneously rather than one at a time. The Quik-Cap works in the same manner as the predicate device. The Quik-Cap has the same technological characteristics as the predicate device.

The Quik-Cap design is in conformance with AAMI Standard Specifications for ECG Cables and Lead-wires and Other Devices that use Patient Cables, EC53-1995, and the IEC Standard 60601-1 subclause 56.3, (c). Like the predicate device, the Quik-Cap consists of a stretchable fabric cap, metal disk electrodes, electrode holders, and electrode lead wires.

Technologically, the Quik-Cap functions in exactly the same manner as the predicate device, however the device differs from the predicate in two ways. The electrode holders are made of soft rubber rather than hard plastic and the wires are maintained on the outside of the cap rather than on the inside. The soft rubber holders are to increase patient comfort, particularly when lying down. The design/placement of the electrode lead wires on the outside of the cap allows the cap to be donned and fitted more easily, and prevents the wires from interfering with electrode placement.

III. DECLARATION of CONFORMANCE with CONSENSUS STANDARDS

The electrode positioning cap intended to be introduced conforms in all respects with the requirements of the current addition of AAMI Standard Specifications for ECG Cables and Lead-wires and Other Devices that use Patient Cables, EC53-1995, and the IEC Standard 60601-1 subclause 56.3, (c).

CDRH Guidance Document on the "Performance Standard for Electrode Lead Wires and Patient Cables," March 9, 1998.

Requirement*◊

1. Any connector in a lead having a CONDUCTIVE CONNECTION to a PATIENT shall be constructed in such a manner that no CONDUCTIVE CONNECTION of that part of the said connector which is remote from the PATIENT can contact earth or possibly hazardous voltages.

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* AAMI – Association For the Advancement of Medical Instrumentation, 3330 Washington Blvd., Arlington, VA 22201-4598. Refer to the full text of AAMI EC53-1995 for the specific requirements that apply.

◊ Certifying signature required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2000

Mr. David B. Jones
Regulatory Affairs and
Quality Assurance Manager
Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, Virginia 20166

Re: K000865
Trade Name: Quick Cap EEG Electrode Positioning System
Regulatory Class: II
Product Code: IKS
Dated: March 17, 2000
Received: March 17, 2000

Dear Mr. Jones:

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,

for 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

XIV. INDICATIONS FOR USE STATEMENT

510(k) Number: K000865

Device Name: Quik-Cap EEG Electrode Positioning System

Indications For Use: The Quik-Cap is intended for routine clinical settings where rapid placement of large numbers of EEG electrodes is desired.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000865

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)