Attachment C:

K072016

510(k) Summary

Manufacturer:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands
Submitted by:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands Tel.: (+31) 43-408 6868 Fax: (+31) 43-408 6888
Contact person:	Mr. Maurice Roost Manager Research & Development E-mail: mroost@technomed.nl
Date:	07 September, 2007
Proprietary Name:	Cutaneous Electrodes
Common/usual Name:	Cup Electrodes
Classification Name:	Cutaneous Electrode is classified as class II per 21 CFR section 882.1320. Product code GXY.
Substantial Equivalence:	K061148: Rhythmlink Disc Electrodes
Device description:	A cutaneous electrode is an electrode that is applied directly to a patient's skin to record physiological signals. In other words cutaneous devices are used in the acquisition of signals for the purpose of monitoring and recording Electroencephalograph (EEG), Electroencephalography (EEG), and Evoked Potentials (EP) and the electroencephalographic/evoked potentials reading is a completely non-invasive procedure that can be applied repeatedly to patients, normal adults, and children with virtually no risk or limitation. The electrodes are delivered non sterile and are available in reusable and disposable versions.
Reusable:	Reusable Cup Electrodes have a disc manufactured with a variety of materials which include: silver, Ag/AgCl, Gold Plated. The disc is permanently adhered to a lead wire. The insulated lead wires terminate using a molded touch proof connector (DIN 42-802) for electrical safety. The cup electrode may be sterilized using steam autoclave. The cup electrodes are available in an adult version and a pediatric version.
Disposable:	These electrode are for single patient use only. Disposable Cup Electrodes have a disc manufactured of molded ABS, Ag/AgCl Plated. The disc is permanently adhered to a lead wire. The insulated lead wires terminate using a molded touch proof connector (DIN 42-802) for electrical safety.

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Intended Use:	The Cup Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials (EP).
Comparison to predicates:	The design, materials, chemical composition, packaging and other technological characteristics of the subject device is equivalent to those of the predicate devices.
Non-clinical data:	Technomed Europe has been bench testing the Cup Electrodes to confirm performance characteristics of this device.
Conclusion:	The comparison to the predicate devices demonstrate that the cup electrodes are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2007

Technomed Europe
c/o Mr. Maurice Roost, Manager Research & Development
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Re: K072016
Trade/Device Name: Cup Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode.
Regulatory Class: Class II
Product Code: GXY
Dated: July 20, 2007
Received: July 23, 2007

Dear Mr. Roost:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for DEP D.R. 10/19/15

Mark N. Melkerson
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):

Device Name: Cup Electrodes

Indications For Use:

The Cup Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 k012014