K053363

MAY 30 2006

510(k) Summary

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|---|---|
| Company Name: | AD-TECH Medical Instrument Corporation<br>1901 William Street<br>Racine, WI 53404 1876 |
| Contact:<br>Phone:<br>Fax: | John Ziobro, Chief Operating Officer<br>262 367-9200, ext. 101<br>262 367-9149 |
| Summary Date: | November 22, 2005 |
| Trade Name: | Subdural Electrodes (Dual-Sided Interhemispheric, Grid, Intraoperative, Strip, Wyler) |
| Common Name: | Cortical Electrodes |
| Classification Name: | 21 CFR 882.1310, Cortical Electrode |

Predicate Device(s):

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| 510(k) Number: | K970587, K923803 |
| Manufacture: | AD-TECH Medical Instrument Corporation |
| Trade Name: | Subdural Electrode |

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| 510(k) Number: | K021144 |
| Manufacture: | Nicolet Biomedical Corporation |
| Trade Name: | Subdural Strip Electrode |

## 1.0 Description of Electrodes

Subdural electrodes described in this application are single patient use, disposable, sterile and non-sterile devices. The electrodes are invasive as they are placed in contact with the brain.

The electrodes provide the patient contact device. The electrodes connect to the user's recording, monitoring and stimulation/response equipment. The electrodes are used under the supervision of a physician. Physicians in the areas of biopotential recording, monitoring and stimulation/response studies understand the use of subdural electrodes.

## 2.0 Intended Use of Electrodes

The AD-TECH Subdural Electrodes (Dual-Sided Interhemispheric, Grid, Intraoperative, Strip, Wyler) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals on the surface of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

## 3.0 Technological Characteristics

The technical characteristics of the Subdural Electrodes are not affected this submission.

## 4.0 Conclusions

The characteristics of the Subdural Electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2006

AD-TECH Medical Instrument Corporation
C/O Mr. Gary Syring
Official Correspondent for AD-TECH Medical Instrument Corporation
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K053363
Trade/Device Name: AD-TECH Subdural Cortical Electrodes
(Dual-Sided Interhemispheric, Grid, Intraoperative, Strip, Wyler)
Regulation Number: 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: II
Product Code: GYC
Dated: March 27, 2006
Received: March 28, 2006

Dear Mr. Syring:

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.

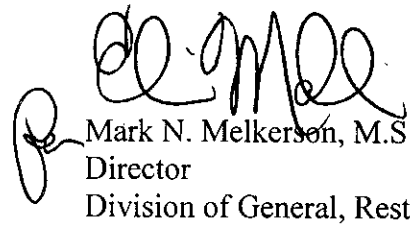
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# Indications for Use

510(k) Number (if known): _____

Device Name: Subdural Electrodes

Indications for Use:

The AD-TECH Subdural Electrodes (Dual-Sided Interhemispheric, Grid, Intraoperative, Strip, Wyler) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals on the surface of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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** K053363