SEP 1 3 1999

K992194

510(k) SUMMARY - 21 CFR 807.92

A. EXECUTIVE SUMMARY

This 510(k) Premarket Notification, details AD-TECH Medical Instrument Corporation's Model CMU Cortical Mapping Unit. Its indication for use is to facilitate the recording of EEG potentials from the surface of the exposed human brain during surgery. It is an enhanced version of a pre-amendment device. The CMU and is not implanted, but does need to be EtO sterilized prior to each use.

B. APPLICANT INFORMATION

Applicant's Name: AD-TECH Medical Instrument Corporation
Address: 1901 William Street, Racine, WI 53404 USA
Contact Person: John Ziobro, COO
Telephone: (262)* 634-1555
Fax: (262)* 634-5668

Signature of Applicant: 6.24.99

John Ziobro, COO (date)

*OUR AREA CODE WILL REMAIN (414) UNTIL SEPTEMBER 25, 1999

C. DEVICE INFORMATION

1. TRADE NAME	Model CMU Cortical Mapping Unit
2. COMMON NAME	Cortical Electrode
3. FDA REGISTRATION NUMBER	2183456
4. MANUFACTURING ADDRESS	1901 William Street, Racine, WI 53404 This product and its accessories are shipped non-sterile, therefore no sterilization sites are listed.
5. PRODUCT CODE & CLASSIFICATION	84GYC, CLASS II (21 CFR 882.1310)
6. REASON	New Device
7. EQUIVALENT DEVICE	Model CE-1 Cortical Electrode. Grass Instruments (Astro-Med) 600 East Greenwich Avenue, West Warwick, RI 02893 (marketed before May 28th, 1976)
8. PERFORMANCE STANDARD	None established under Section 514

D. SAFETY & EFFECTIVENESS INFORMATION

1. GENERAL SAFETY & EFFECTIVENESS CONCERNS

a. AD-TECH's labeling contains instructions for the proper use of this product. It includes a description of the product, directions for use, and applicable safety information. These instructions ensure safe and effective use of the device when followed by the physician.

2. DESCRIPTION OF THE DEVICE & BASIS OF SUBSTANTIAL EQUIVALENCE.

a. AD-TECH's Model CMU Cortical Mapping Unit has similar intended uses, materials and technological characteristics as the predicate device. There are only three differences of note:
   (1) Our electrode plates are made of clear Lexan plastic while theirs are stainless steel. We maintain that the clear plates are a marketing feature.
   (2) Our electrodes are made of stainless steel; theirs use cotton wicks.
   (3) Our device is sterilized via EtO; theirs may be autoclaved.

b. None of these difference are material to the safety & effectiveness of the device.

c. Both devices have identical indications for use, namely to facilitate the recording of EEG potentials from the surface of the exposed human brain during surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 1999

Mr. John F. Ziobro
Chief Operating Officer
Ad-Tech Medical Instrument Corporation
1901 William Street
Racine, Wisconsin 53404

Re: K992194
Trade Name: Model CMU Cortical Mapping Unit
Regulatory Class: II
Product Code: GYC
Dated: June 24, 1999
Received: June 29, 1999

Dear Mr. Ziobro:

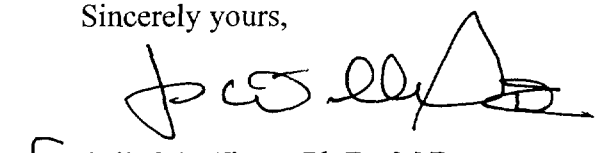
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

510(k) Number if Known: Unknown K992194

Device Name: Model CMU Cortical Mapping Unit

Indications For Use:

"The use of the Model CMU Cortical Mapping Unit is indicated where intraoperative, short-term recording of cortical surface EEG activity is required."

"AD-TECH's CMU, like other cortical mapping instruments, is designed to facilitate the recording of EEG potentials from the surface of the brain during surgery. This EEG information can help guide your progress during tumor resections, epilepsy surgery, etc."

"This device should only be used by physicians/surgeons trained in the use of cortical mapping devices."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use____
(Per 21 CFR 810.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992194