K041604

AUG 16 2004

Summary of Safety and Effectiveness

Company Name:	AD-TECH Medical Instrument Corporation 1901 William Street Racine, WI 53404 1876
Contact: Phone: Fax:	John Ziobro, Chief Operating Officer 262 367-9200, ext. 101 262 367-9149
Summary Date:	August 2, 2004
Trade Name:	Macro-Micro Depth Electrodes
Common Name:	Depth Electrodes
Classification Name:	21 CFR 882.1330, Depth Electrode

Predicate Device(s):

510(k) Number:	K891920, K964644
Manufacture:	AD-TECH Medical Instrument Corporation
Trade Name:	Depth Electrode
Product Code:	GZL

510(k) Number:	K033173
Manufacture:	Fhc, Inc.
Trade Name:	Micro Targeting Electrode
Product Code:	GZL

1.0 Description of Electrodes

Depth 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 nerve tissue.

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 depth electrodes.

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2.0 Intended Use of Electrodes

The Macro-Micro Depth Electrodes are intended for use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.

3.0 Technological Characteristics

The main components of the depth electrodes are:

1. Contract strip with macro depth electrode contacts and connector contacts;
2. Stylet;
3. Inner lumen;
4. Micro wire electrode(s) for insertion and placement through the macro electrode inner lumen.

The lead wires terminate in a safety connector that cannot be connected to an AC power outlet. The materials are the same as used in the predicate devices and/or are common to depth electrodes.

4.0 Conclusions

The characteristics of the Macro-Micro Depth 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

AUG 16 2004

Ad-Tech Medical Instrument Corporation
c/o Mr. Gary Syring
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K041604
Trade/Device Name: Macro-Micro Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: II
Product Code: GZL
Dated: June 11, 2004
Received: June 15, 2004

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
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): K041604

Device Name: Macro-Micro Depth Electrodes

Indications for Use:

The Macro-Micro Depth Electrodes are intended for use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.

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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041604