NOV - 2 1999

K990788

510(k) Summary

Summary of Safety and Effectiveness

I. General Information

Common Name:	Depth Electrode
Device Trade Name:	Ad-Tech's Foramen Ovale Electrode
Classification:	Class II 882.1330 Depth Electrode
Intended Use:	Ad-Tech's Foramen Ovale/Depth Electrode is intended for intra-operative monitoring (for surgical use only / not intended for implantation) and eeg recording of electrical signals of the brain for epilepsy monitoring.
Predicate Device:	Ad-Tech's Depth Electrode 510(k) K891920 B
Manufacturing Facility Address:	Ad-Tech Medical Instrument Corp. 1901 William Street Racine, WI 53404
Performance Standard:	No applicable performance standards have been issued under section 514 of the Food, Drug, and Cosmetic Act.
Establishment Registration Number:	2183456
Product Code/Classification Panel:	84GYC & 84GZL/Neurology
Contact Name:	David Putz 414-634-1555 Ad-Tech Medical Instrument Corp. 1901 William Street Racine, WI 53404

II. Safety and Effectiveness Information Supporting the Substantial Equivelance Determination.

A summary of the information contained in this "PMN" that addresses saftey and effectiveness follows.

General Safety and Effectiveness Concerns

Ad-Tech's Foramen Ovale Electrode'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.

Description of the Device and Basis for Substantial Equivalence

Ad-Tech's Foramen Ovale Electrode has similar intended uses, naterials, technological characteristics, sterilization procedures, and packaging as the commercially available Ad-Tech Depth Electrode (K 891920B). The Foramen Ovale Electrodes are used for intra-operative monitoring (for surgical use only / not for implantation) and recording of electrical brain signals for epilepsy monitoring on the surface and sub-surface of the brain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 1999

Mr. David Putz
Ad-Tech Medical Instrument Corporation
1901 William Street
Racine, Wisconsin 53404

Re: K990788
Trade Name: Ad-Tech's Foramen Ovale Electrode
Regulatory Class: II
Product Code: GZL
Dated: August 30, 1999
Received: August 31, 1999

Dear Mr. Putz:

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) 594-4659. 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

510(k) Number (if known): unknown

Device Name: Ad-Tech's Foramen Ovale Electrode

Indications For Use:

The foramen ovale electrode is designed for monitoring brain electrical activity (eeg) or defining the location of epileptogenic foci in patients with intractable epilepsy. The foramen ovale electrode is intended for "Surgical Use Only" and "Not Intended for Implantation" This product should only be used by a physician/surgeon trained in the use of foramen ovale electrodes.

(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 Devices
510(k) Number K990788

Prescription Use ✓ OR Over-The Counter Use__
(Per 21 CFR 801.109)

(Optional Format 1-2-96)