

JUN 10 1998

K973454

AD-TECH MEDICAL INSTRUMENT CORPORATION

510(k) Summary

April 20, 1998

I. General Information

Contact Name and Manufacturing Address:	Curtis Van Allen II Ad-Tech Medical Instrument Corp. 1901 William Street Racine, WI 53404 Tel. (414) 634-1555 Fax. (414) 634-5668
Device Trade Name:	Ad-Tech's Spinal Electrode
Common Name:	Electrode, Cortical
Classification:	Class II 882.1310 Cortical Electrode
Intended Use:	Ad-Tech's Spinal Electrode is intended for measurement of muscle MEP (Motor Evoked Potential) type monitoring during spinal surgery.
Predicate Device:	Nicolet Epidural Spinal Electrode (K882053)
Product Code / Classification:	84GYC
Establishment Registration Number:	2183456

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

1901 WILLIAM STREET RACINE, WISCONSIN 53404, U.S.A.
TELEPHONE 414-634-1555
TELEFAX 414-634-5668

General Safety and Effectiveness Concerns

Ad-Tech Spinal Electrode 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 promote safe and effective use of the device when followed by a physician.

Description of the Device and Basis for Substantial Equivalence

The Ad-Tech Spinal Electrode addressed in this premarket notification has identical materials, technological characteristics, sterilization procedures and packaging as the commercially available Ad-Tech Depth Electrode (K891920B). The device has similar intended use, materials and technological characteristics to the commercially available Nicolet Epidural Spinal Electrode (K882053). Like this device, the Ad-Tech Spinal Electrode is to be placed epidurally for monitoring evoked potentials. Ad-Tech believes that the information provided in this premarket notification clearly demonstrate that it is safe and equivalent to the mentioned commercially marketed predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Curtis Van Allen II
Vice President
Director of Marketing and Planning
Ad-Tech Medical Instrument Corporation
1901 William Street
Racine, Wisconsin 53404

Re: K973454
Trade Name: Ad-Tech's Spinal Electrode
Regulatory Class: II
Product Codes: GZL, GWF, and JXE
Dated: April 24, 1998
Received: May 11, 1998

Dear Mr. Allen:

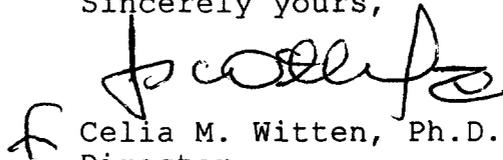
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



f 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

Indications for Use

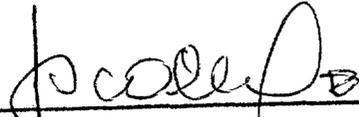
510K Number:

Device Name: Ad-Tech's Spinal Electrode

Indications for Use: Ad-Tech's Spinal Electrode is intended for measurement of muscle MEP (Motor Evoked Potential) type monitoring during spinal surgery.

Prescription Use _____
(Per 21 CFR 801.109)

7



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

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