

MAR - 1 2000

510(k) Summary

K994097

MedAmicus Epidural Introducer

Date of Preparation: October 29, 1999

General Information

Trade Name	MedAmicus Epidural Introducer
Classification Name	Introducer, Percutaneous §870.1340
Common Name	Percutaneous Introducer
Submitter	MedAmicus, Inc. 15301 Highway 55 West Minneapolis, MN 55447
Contact	Dennis S. Madison Vice President, Quality Assurance/Regulatory Affairs 612-559-2613, Fax: 612-559-7548

Predicate Devices

Coaxial Dilator from MedAmicus, Inc. (K990705)
Introde INT-8 from ANS (Neuromed), Inc. (K930242)

Device Description Information

Intended Use

The MedAmicus Epidural Introducer is intended to be used in the same manner as the ANS (Neuromed) Introde INT-8 cleared by the FDA under K930242 and in a similar manner to the Coaxial Dilator manufactured by MedAmicus, Inc. and cleared by the FDA under K990705. The intended use of these introducers is for percutaneous introduction, manipulation, and removal of epidural stimulation leads.

Conclusion

MedAmicus believes the MedAmicus Epidural Introducer is safe and effective based on substantial equivalence to the predicate MedAmicus and ANS Introducer Sheaths. The intended use, materials, labeling, method of operation and manufacturing methods are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Dennis S. Madison
Vice President, Quality Assurance
and Regulatory Affairs
MedAmicus, Inc.
15301 Highway 55 West
Minneapolis, Minnesota 55447

Re: K994097
Trade Name: MedAmicus Epidural Introducer
Regulatory Class: II
Product Code: GZB
Dated: November 29, 1999
Received: December 3, 1999

Dear Mr. Madison:

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.

Page 2 – Mr. Dennis S. Madison

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,



sv James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

K 994097

For percutaneous introduction, manipulation, and removal of epidural stimulation leads.

Contraindications

None



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K 994097

Prescription Use
(Per 21 CFR 801.109)