JAN 2 4 2002

510(k) Summary Dated 1/15/02

General Information

Classification: Class II

Trade Name: Percutaneous Introducer Set

Submitter: MedAmicus, Inc.
15301 Highway 55 West
Minneapolis, MN 55447

Contact: Karyl Haskell
Quality and Regulatory Affairs Manager
763-577-2257

Device Identification

A. Device Proprietary Name

Percutaneous Introducer Set

B. Device Common name

Percutaneous Introducer

C. Device Classification name and reference

Therapeutic Devices, Neurological
Reference 882.5880

Sec. 882.5880 Implanted spinal cord stimulator for pain relief.

(a) Identification. An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.
(b) Classification. Class II (performance standards).

D. Device proposed regulatory class

Class II

E. Device product code

GZB

F. Classification Panel

Neurological

G. Device Performance Standards

To date no special controls have been established for these devices. Performance standards as required by Section 514 of the Federal Food, Drug and Cosmetic act and implemented by 21CFR Part 861 have not been established for percutaneous introducer sets.

Predicate Device

MedAmicus Epidural Introducer (K994097)

Device Descriptive Information

General Description

The Percutaneous Introducer Set is a single use device allowing for introduction, manipulation, and removal of stimulation leads after percutaneous entry is gained with a needle. The sheath is made of HDPE (High Density Polyethylene) with a HDPE hub. It is slightly tapered at the distal end to make a smooth transition to the dilator. The dilator is made of 304 stainless steel tubing tapered at the distal end for smooth insertion. It has a molded HDPE hub. The guidewire directional guide is made of 304 stainless steel wire with radiuses at each end. It has depth markings etched into the surface along the distal end.

Intended Use

The Percutaneous Introducer Set is intended for percutaneous introduction, manipulation, and removal of stimulation leads

Biocompatability

Per ISO 10993 this device is classified as Externally Communicating – Tissue/Bone/Dentin Communicating – Limited Exposure. Applications referred to below are for Externally Communicating – Blood Path Indirect – Limited Exposure which includes all the testing required above.

Materials used in the Percutaneous Introducer Set are identical to materials previously approved/cleared for market release. The materials of the sheath, sheath hub, and dilator hub are identical to those used in the MedAmicus Coaxial Introducer (K990705) which is a predicate device for the Epidural Introducer. Both the Epidural and Coaxial Introducer use HDPE with the exception that the Epidural Introducer uses a blue dye in the sheath shaft. The 304 stainless steel use in the dilator shaft and directional guide is identical to the cannulas of Medtronic foramen needles (P970004). The platinum iridium used as a marker band in the introducer sheath is identical to the electrodes of Medtronic stimulation leads (P970004). Since the materials are identical to those previously approved/cleared, there are no new issues involving safety and effectiveness.

Device Performance/Product Testing

Performance data indicates that the Percutaneous Introducer Set meets the functional requirements and specifications for this device.

Technology Characteristics

The device is equivalent technologically to the device mentioned under predicate device above.

Substantial Equivalence

Substantial Equivalence Discussion

The Percutaneous Introducer Set is intended for percutaneous introduction, manipulation, and removal of stimulation leads. The intended use, basic design, methods of manufacturing, and materials are similar to the predicate device, the MedAmicus Epidural Introducer.

The sheath materials and manufacturing processes for the Percutaneous Introducer Set are equivalent to those used on the predicate MedAmicus device, the MedAmicus Epidural Introducer (K994097). The 304 stainless steel use in the dilator shaft and guidewire has been used in numerous applications and in particular by Medtronic (P970004) in the cannulas of their foramen needles. The platinum iridium has also been used in numerous applications and in particular by Medtronic (P970004) in the electrodes of their leads.

The packaging materials for the Percutaneous Introducer Set are equivalent to the predicate MedAmicus Epidural Introducer. These materials consist of a double sterile barrier using Tyvek/Mylar pouches. Present sterilization cycle assures a Sterility Assurance Level (SAL) of $>10^{-6}$.

Substantial Equivalence Conclusion

The Percutaneous Introducer Set is intended for percutaneous introduction, manipulation, and removal of stimulation leads. The basic design, methods of manufacturing, and materials used are substantially equivalent to the predicate device, MedAmicus Epidural Introducer (K994097). The application of this device is substantially equivalent to the aforementioned device already cleared for market release. The clinical indications for use remain unchanged. MedAmicus

believes the Percutaneous Introducer Set is substantially equivalent to currently marketed medical introducers employing the same technology and is therefore safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2002

Ms. Karyl Haskell
Quality Assurance & Regulatory
Affairs Manager
Medamicus, Inc.
15301 Highway 55 West
MINNEAPOLIS, MN 55447

Re: K013120
Trade/Device Name: Model 042294 Lead Introducer Set and Model 3550-18 Lead Introducer Kit
Regulation Number: 21 CFR §882.5880
Regulation Name: Implanted spinal cord stimulator for pain relief
Regulatory Class: II
Product Code: 84 GZB
Dated: December 14, 2001
Received: December 17, 2001

Dear Ms. Haskell:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Applicant: MedAmicus, Inc.
510(k) Number (if known): New Submission K013120
Device Name: Model 042294 and 3550-18 Percutaneous Introducer Set
Indications For Use:

The Percutaneous Introducer Set is indicated for percutaneous introduction, manipulation, and removal of stimulation leads.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013120

Prescription Use
(Per 21 CFR 801.109)