K990705

JUN 2 8 1999

510(k) Summary

MedAmicus Coaxial Introducer

General Information

Classification	Class II
Trade Name	MedAmicus Coaxial Introducer
Submitter	MedAmicus, Inc. 15301 Highway 55 West Minneapolis, MN 55447
Contact	Dennis S. Madison Vice President, Quality Assurance/Regulatory Affairs 612-559-2613

Predicate Devices

Percutaneous Introducers from MedAmicus, Inc. (K932323)
Coaxial Introducers from Boston Scientific, Inc. (K974640)

Device Description Information

Intended Use

The MedAmicus Coaxial Introducer is intended to be used in the exact same manner as the Boston Scientific Coaxial Introducer cleared by the FDA under K974640 and in a similar manner to introducers manufactured by MedAmicus, Inc. and cleared by the FDA under K932323. The intended use of these introducers is to introduce up to a 0.038 inch guide wire or catheter into the vascular system following a small 21 gauge needle stick.

Device Description

The proposed coaxial introducer set consists of an inner dilator within a slightly shorter outer sheath. The inner dilator is high density polyethylene and has length of approximately 4.5 inches. The outer sheath is also high density polyethylene and is approximately 3.5 inches long. The inner dilator and outer sheath are radiopaque so that they are visible under fluoroscopy. The hub on the inner dilator is high density polyethylene. The hub on the outer sheath is also high density polyethylene. The set may be 4F, 4.5F or 5F.

The kit contains a 21 gauge disposable aspiration and injection needle, a .018 inch diameter guidewire, and a Coaxial Introducer Set consisting of a sheath and dilator.

Material Information

The proposed coaxial introducer set consists of a sheath and a dilator. The dilator uses the identical materials as those used in MedAmicus' legally marketed dilators. The sheath material for the proposed device is high density polyethylene identical to that used in the dilator with the exception that it has a durometer of 66 rather than 65 for increased stiffness. The material is produced by the same manufacturer. Materials for the sheath and dilator are processed using equivalent processing technologies as for the predicate device.

Biocompatability testing was conducted on MedAmicus' peelable sheath and dilator that uses identical material to that used in the Coaxial Introducer. Testing included all tests required to be conducted in FDA's modified ISO-10993 standard for the biological evaluation of medical devices. These included: acute systemic toxicity, acute intracutaneous toxicity, cytotoxicity, hemolysis, rabbit pyrogen and sensitization.

Device Performance/Product Testing

Testing of bonding strength between the inner dilator and its hub and the outer sheath and its hub was conducted on sterilized, finished devices to ensure acceptable joint integrity. Boston Scientific's coaxial dilator set was also tested to provide a basis for determining substantial equivalence for the mechanical properties of the proposed device. All samples met the required specifications.

Sterilization and Packaging Information

The sterilization cycle for the MedAmicus Coaxial Introducer kit is identical to the cycle for the predicate MedAmicus introducers. The ETO sterilization cycle for these products was validated using the AAMI method of three half cycles and one full cycle.

Validation tests were performed with spore strips (one million spores of Bacillus var niger) placed in sample product and sterilized at one half the regular cycle. The results showed a complete kill which proves a Sterility Assurance Level (SAL) of greater than 10^{-6}.

The packaging materials for the MedAmicus Coaxial Introducer Kit are identical to the predicate MedAmicus product. These materials consist of a single sterile barrier using a Tyvek/Mylar pouch.

Substantial Equivalence

The MedAmicus Coaxial Introducer is intended to introduce up to a 0.038 inch guide wire or catheter into the vascular system following a small 21 gauge needle stick. The basic design, methods of manufacturing, and materials used are similar to existing MedAmicus introducer kits and Boston Scientific Coaxial introducers cleared by the FDA. Our application of these devices is substantially equivalent to the aforementioned standard medical procedures already approved for use. The clinical indications for use remain unchanged. MedAmicus believes the MedAmicus Coaxial Introducer is substantially equivalent to currently marketed medical introducer devices employing the same technology.

Conclusion

In conclusion, MedAmicus believes the MedAmicus Coaxial Introducer is substantially equivalent to the predicate MedAmicus and Boston Scientific introducer sets. The intended use, materials, labeling, method of operation and manufacturing methods are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 1999

Mr. Dennis S. Madison
Medamicus Corporation
15301 Highway 55 West
Minneapolis, MN 55447

Re: K990705
Coaxial Introducer
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: May 5, 1999
Received: June 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 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). 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 requirements, 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990705

Device Name: COAXIAL INTRODUCER

Indications for Use

The coaxial introducer set is indicated for use to introduce up to a 0.038 inch guide wire or catheter into the vascular systems following a small 21 gauge needle stick.

(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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

(Optional Format 3-10-98)

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