



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Mr. Jeffrey A. McBroom  
Development Engineer  
MedAmicus, Inc.  
15301 Highway 55 West  
Minneapolis, Minnesota 55447

JUL 25 1997

Re: K965167  
Percutaneous Venous Introducer  
Regulatory Class: II (two)  
Product Code: DYB  
Dated: April 24, 1997  
Received: April 28, 1997

Dear Mr. McBroom:

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.

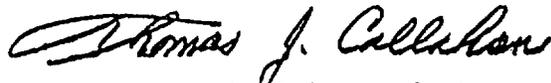
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4648. 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/dsmamain.html>".

Sincerely yours,



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

Enclosure

K965167

## 510(k) Summary

### MedAmicus Percutaneous Introducer

#### General Information

Classification	Class II	JUL 25 1997
Trade Name	MedAmicus Percutaneous Introducer	
Submitter	MedAmicus, Inc. 15301 Highway 55 West Minneapolis, MN 55447	
Contact	David A. Liebl Director of Research and Development (612) 559-2613	

#### Predicate Devices

Percutaneous introducers from MedAmicus, Inc.

### Device Description Information

#### Intended Use

The MedAmicus Percutaneous Introducer is intended to be used in the exact same manner as the previous introducers manufactured by MedAmicus and cleared by FDA under K893658 and K951313. The intended use of these introducers is to create a percutaneous pathway for the introduction of catheters, ports, and pacing leads into the venous vasculature. The MedAmicus Percutaneous Introducer is packaged with the exact same components as the previous introducers. The package contents are a needle, a disposable syringe, and a flexible guidewire.

#### Device Description

The MedAmicus Percutaneous Introducer package consists of a thin-wall needle, a disposable syringe, and a flexible guidewire. Percutaneous introducers are small diameter tubular shaped devices with an integrated proximal handle. These MedAmicus

introducers all have a feature for removal common to introducers. This feature allows the user to remove the introducer without removing the inserted catheter or pacing lead. The design of the MedAmicus Percutaneous Introducer incorporates a nylon braiding material in the wall of the sheath which improves kink resistance and a marker band near the distal tip to assist in introducer tip location during the pacing lead, catheter, or infusion port introduction process under fluoroscopy.

The materials used in the manufacture of the MedAmicus Percutaneous Introducer are identical to those used in the other MedAmicus introducers cleared by FDA with the exception of the addition of the nylon braiding material within the wall of the sheath tubing and the attachment of a Platinum/Iridium marker band near the distal tip. These additional materials, however, are standard in other medical devices used in a variety of arterial procedures in the body. The methods of manufacture and sterilization are the same as well. The clinical indications, labeling, and packaging remain unchanged from the predicate MedAmicus devices.

### **Materials**

The materials which are new to this device which are the nylon braiding material within the wall of the sheath and the Platinum/Iridium marker band near the distal tip. These additional materials have been fully evaluated in terms of biocompatibility and performance towards the end use of the device and successfully passed these evaluations. All other materials used in this product are identical to the predicate MedAmicus Introducer product which has already been approved. All MedAmicus Percutaneous Introducer packages are supplied sterile.

### **Device Performance / Product Testing**

Sample devices were subjected to physical bench testing. Tests included visual examination for workmanship, improved kink resistance testing via radius models, and marker band removal integrity and security evaluations. All samples met the required specifications.

## **Sterilization Information**

The sterilization cycle for the MedAmicus Percutaneous Introducer 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 of greater than one in one million devices being non-sterile.

## **Packaging**

The packaging materials for the MedAmicus Percutaneous Introducer package are identical to the predicate MedAmicus products. The product is placed in a PETG kit and then sealed with a Tyvek lid. The sealed tray is then placed within a sealed Tyvek Pouch. The sterile product is then placed with appropriated labeling and instructions for use in a carton for shipping. An additional packaging configuration has been approved as part of 510(k) # K951313 which involves a polystyrene tray which is placed within a sealed Tyvek pouch.

## **Substantial Equivalence**

The MedAmicus Percutaneous Introducer is intended to create a percutaneous pathway for the introduction of catheters, ports, and pacing leads into general vasculature. The basic design, methods of manufacturing, and materials used are identical to existing MedAmicus introducer sheaths cleared by FDA. The additional features in terms of braided re-enforcement sheath tubing and an integral marker band for distal tip location are standard technologies which have been used for many years in the medical industry in very similar applications such as hemostasis valves with braided tubing, guide catheters which utilize braided tubing, and angioplasty catheters with marker bands near the balloons to identify balloon location during the angioplasty procedure. Our application of these technologies is substantially equivalent to the aforementioned standard medical procedures already approved for use. The clinical indications for use remain unchanged. MedAmicus believes the MedAmicus Percutaneous Introducer is

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substantially equivalent to currently marketed medical introducer devices employing the same technology.

## **Conclusion**

In conclusion, MedAmicus believes the MedAmicus Percutaneous Introducer is substantially equivalent to the predicate MedAmicus percutaneous introducer sheaths and other introducer technologies which incorporate braided reinforced tubing and radiopaque marker bands. The intended use, materials, sterilization, packaging, labeling, method of operation and manufacturing methods are substantially equivalent.

## Indications for Use

The MedAmicus Percutaneous Introducer is indicated for use to access the venous side of the circulatory system to create an access port to conduct interventional procedures with catheters or implant long or short term interventional devices.

*Tara A R*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number

K965167