K101399

JUN 17 2010

510(k) SUMMARY

A. Submitter Information:

Submitter:	MARTECH MEDICAL PRODUCTS 1500 Delp Drive Harleysville, PA 19438 (215) 256-8833 Telephone (215) 256-9191 Fax
Contact:	Susan Pileggi
Date Prepared:	May 17, 2010

B. Device Name: Coaxial Introducer Set

Common Name:	Introducer Set
Classification Name:	Catheter Introducer (74 DYB)
C.F.R. Section:	880.1340
Class:	II

C. Predicate Devices: **K091954:** Medcomp, Micro-Stick Set

D. Device Description:

The Coaxial Introducer Set is designed to provide dilation of the initial entry point and provide a channel for attaining vascular access. The coaxial introducer consists of an inner dilator within a slightly shorter outer sheath.

The kit contains a 21 gauge introducer needle, a .018" diameter guidewire, and a 4F or 5F coaxial introducer. The coaxial introducer is offered in a standard and stiff version.

The Coaxial Introducer Set is provided in sterile and non-sterile configurations.

E. Intended Use:

The Coaxial Introducer Set is indicated for percutaneous introduction of up to a 0.038 inch guidewire or catheter into the vascular system following a small 21 gauge needle stick. The Coaxial Introducer Set is not intended for use in the coronary or cerebral vasculature.

F. Comparison to Predicate Devices:

The Coaxial Introducer Set is substantially equivalent to the predicate devices in terms of intended use, anatomical location, general design, and method of sterilization.

G. Bench / Performance Data:

The following in-vitro testing was performed on the Coaxial Introducer Set to assure reliable design and performance in accordance with ISO standards and/or internal procedures.

- Guidewire Passage
- Air Leakage
- Liquid Leakage
- Force at Break
- Simulated Use

H. Biocompatibility:

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993.

I. Conclusion:

The proposed devices meet the performance criteria of design verification as specified by ISO standards and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed devices are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 17 2010

Martech Medical
c/o Ms. Susan Pileggi
Regulatory Specialist
1500 Delp Drive
Harleysville, PA 19438

Re: K101399
Trade/Device Name: Coaxial Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: Class II (two)
Product Code: DYB
Dated: May 17, 2010
Received: May 26, 2010

Dear Ms. Pileggi:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101399

Device Name: Coaxial Introducer Set

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vichinsky

(Division Sign-Off)
Division of Cardiovascular Devices

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