MARTECH
MEDICAL PRODUCTS

K120617

NOV 19 2012

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:	Alexis Erazo
Date Prepared:	March 1, 2012

B. Device Name: PTFE Super Sheath Introducer

Common Name:	Super Sheath
Classification Name:	Catheter Introducer (74 DYB)
C.F.R. Section:	870.1340
Product Code and Class:	DYB; II

C. Predicate Devices:

K000313: Xentek, Tearaway Introducer Sheath
K053092: Medcomp, Vascu-Sheath II
K090394: Medcomp, Valved Tearaway Introducer

D. Device Description:

The PTFE Super Sheath Introducer with Sheath/Dilator assembly facilitates vascular access for placement of intravascular catheters. Inserting an introducer needle into the desired vessel allows for initial access to the vascular system. A guide wire is then placed into the vessel through the needle and the needle is then removed. The sheath/dilator assembly is then inserted over the guide wire and into the percutaneous opening to dilate the opening into the vessel. The dilator and guide wire are then removed leaving the sheath in place. A catheter can then be placed through the sheath. Breaking the sheaths hub and peeling the sheath away from the catheter then allows the sheath to be removed. Its frame is composed of mostly HDPE, as the sheath hub, dilator and dilator hub are all HPDE. The sheath tube is composed of PTFE (Teflon). The Super Sheath if gray in color with the exception of the dilator hub which is composed of a different color to identify each individual French size (3F Purple, 3.5F Pink, 4F Red, 4.5F Yellow, 5F Light Gray, 5.5F Dark Gray, 6F Green, 6.5F Light Green, 7F Orange, 8F Blue, and 9F White). The PTFE Super Sheath is available in eleven (11) different French sizes ranging from 3F to 9F. The Introducers are available 3F-7F with a 5cm length or 3F-9F in the 10cm length option.

E. Intended Use:

Introducer is intended to obtain central venous access to facilitate catheter insertion or placing pacing leads into the central venous system.

F. Indications for Use:

The PTFE Super Sheath Introducers are intended to obtain central venous access to facilitate catheter insertion or placing pacing leads into the central venous system.

G. Comparison to Predicate Devices:

The PTFE Super Sheath Introducer is substantially equivalent to the predicate devices in terms of intended use, anatomical location, general design, and materials.

H. Bench / Performance Data:

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

- Air Leakage
- Liquid Leakage
- Force at Break
- Simulated Use
- Equipment Interaction
- Surface Examination

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 Center – WO66-G609
Silver Spring, MD 20993-002

NOV 19 2012

Martech Medical Products
Ms. Alexis Erazo
Regulatory Specialist
1500 Delp Drive
Harleysville, PA 19438

Re: K120617
Trade/Device Name: PTFE Super Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter, Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 22, 2012
Received: October 23, 2012

Dear Ms. Erazo

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,

Matthew G. Hillebrenner

Digitally signed by Matthew G. Hillebrenner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300213272, cn=Matthew G. Hillebrenner
Date: 2012.11.20 11:49:57 -05'00'

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

Enclosure

Indications for Use

510(k) Number (if known): K120617

Device Name: PTFE Super Sheath

Indications for Use:

The PTFE Super Sheath Introducers are intended to obtain central venous access to facilitate catheter insertion or placing pacing leads into the central venous system.

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-
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120617