



February 12, 2016

Courtney Nix  
Regulatory Associate  
MedComp (Medical Components, Inc.)  
1499 Delp Dr.  
Harleysville, PA 19438

Re: K153246  
Trade/Device Name: PTFE Super Sheath Introducer 2.1  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter introducer  
Regulatory Class: Class II  
Product Code: DYB  
Dated: January 11, 2016  
Received: January 15, 2016

Dear Ms. Nix:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**Kenneth J. Cavanaugh -S**

for

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)  
K153246

Device Name  
PTFE Super Sheath 2.1

### Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

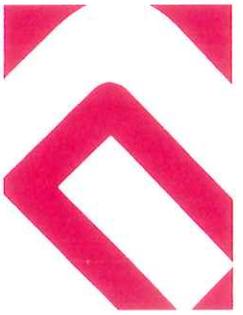
This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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K153246

**Section 9** **510(k) SUMMARY** **Special 510K**

**A. Submitter Information:**

**Submitter:** Medcomp (Medical Components, Inc.)  
1499 Delp Drive  
Harleysville, PA 19438  
(215) 256-8833 Telephone  
(215) 256-9191 Fax

**Contact:** Courtney Nix  
[Cnix@medcompnet.com](mailto:Cnix@medcompnet.com)

**Date Prepared:** 11/3/2015

**B. Device Name:** PTFE Super Sheath Introducer 2.1

**Common Name:** Super Sheath 2.1  
**Classification Name:** Catheter Introducer (74 DYB)  
**C.F.R. Section:** 870.1340  
**Product Code:** DYB  
**Class:** II  
**Sizes:** 3F - 5.5F

**C. Predicate Devices:** K130855  
PTFE Super Sheath Introducer 2.0

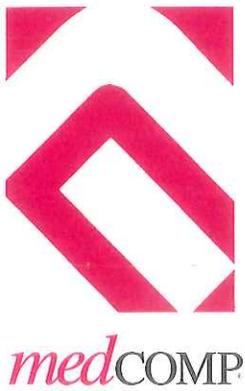
Original Applicant: Martech Medical Products  
Current: Medcomp (Medical Components, Inc)  
Transferred: February 12, 2015

**D. Intended Use:**

The Super Sheath Introducer is intended to obtain central venous access to facilitate catheter insertion or placing pacing leads into the central venous system. The Super Sheath is compatible with a 0.018" or smaller guidewire.

This is the **identical intended use** as previously cleared in PTFE Super Sheath 2.0, K130855.

**E. Indications for Use:**



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

This is the identical indications for use as previously cleared in PTFE Super Sheath 2.0, K130855.

**F. Comparison to Predicate Devices:**

The PTFE Super Sheath Introducer 2.1 is substantially equivalent to the predicate devices in terms of intended use, indications for use, anatomical location, and general design. The sole difference between the predicate device (K130855; Super Sheath 2.0) and the proposed device is the material change to dilatory. The dilator material that was approved in the predicate 510K submission was nylon, the proposed has a dilator composed of a nylon/Pebax blend.

**G. Substantial Equivalence:**

The modified Super Sheath 2.1 has the following similarities to the predicate device (Super Sheath 2.0, K130855):

- Identical indicated use
- Identical indications for use
- Identical operating procedure
- Identical manufacturing processing and sterilization method
- Identical packaging
- Identical design and operation

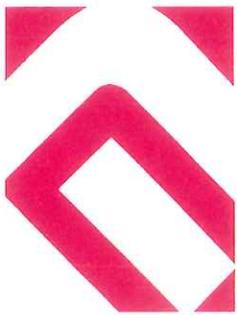
In summary the Super Sheath 2.1, as described with modifications in this submission is, in our opinion, substantially equivalent to the predicate device.

**H. Summary of Design Control Activities:**

A risk analysis was conducted per *ISO 14971 Second Edition 2007-03-01, Medical Devices – Application of Risk Management To Medical Devices (General I (QS/RM))*. The design verification tests that were performed as a result of this risk analysis are listed in Section 10: Bench/Performance Data of this submission (Tables 1-6).

The test methods used are the same as those submitted in the original submission.

A declaration of conformity with design controls is included in this submission



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**I. Labeling:**

There are no changes in the labeling or IFU from the predicate device.

**J. Bench / Performance Data:**

The following in-vitro testing was performed PTFE Super Sheath Introducer v2.1 to assure reliable design and performance in accordance with ISO standards and/or internal procedures. (See Section 10: Bench/Performance Data)

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

**H. Biocompatibility:**

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993. (See Section 11: Biocompatibility)

**I. Software:**

This section is not applicable as the Super Sheath 2.0 does not utilize software.

**J. Sterility Information:**

There are no changes to the sterilization method, or parameters for the proposed device. Sterilization is identical to what was approved for the predicate device, Super Sheath 2.0, K130855.

**K. 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.