K130687

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**Section 5** **510(k) SUMMARY** **Traditional 510K**

**A. Submitter Information:**

Submitter: MEDCOMP®
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Tel: (215) 256-4201
Fax: (215) 256-9191

Contact: Jessica Leo
Regulatory Associate

AUG 15 2013

Date Prepared: March 11, 2013

**B. Trade Name:** Medcomp® Vascu-Sheath Tearaway Introducer

Common Name: Introducer, Catheter

Classification Name: Catheter Introducer (DYB)
Regulation Name: Cardiovascular Devices
C.F.R. Section: 870.1340
Class: II

**C. Predicate Device:** K053092 Medcomp, Vascu-Sheath II

**D. Device Description:**

The Medcomp 2F and 3F Vascu-Sheath Tearaway Introducer is intended for percutaneous venous access by modified Seldinger Technique. The purpose of the device is to facilitate the insertion of a peripheral, mid-line, or central venous catheter. The introducer is inserted over a .010 inch diameter guidewire that has been placed into the target vessel using a needle or IV catheter. Upon placement of the introducer, the guidewire is removed. When the catheter is ready for insertion, the dilator of the introducer is withdrawn from the sheath and the catheter is threaded into the vein through the sheath. When the catheter has been placed, the sheath is simultaneously split and withdrawn leaving the catheter in place.

The Vascu-Sheath Tearaway Introducer is packaged sterile in either a pouch or a variety of tray configurations with additional accessories to facilitate catheter insertion.

**E. Indications for Use:**

The Vascu-Sheath Tearaway Introducer is intended for percutaneous venous access by modified Seldinger Technique in neonates, infants, and children.

**F. Comparison to Predicate Devices:**

The technological characteristics of the Vascu-Sheath Tearaway Introducer are substantially equivalent to the predicate device in terms of intended use, design, performance, placement and method of sterilization.

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**G. Bench / Performance Data:**

Performance data for the Vascu-Sheath Tearaway Introducer demonstrates that this device is substantially equivalent to the legally marketed device.

Performance testing of the proposed devices was conducted in accordance with applicable international standards and FDA guidance documents along with unrecognized ISO standards and internal engineering protocols.

The results of these tests in conjunction with the substantial equivalence claims effectively demonstrate the proposed devices are equivalent to the predicate devices.

The following tests were performed:

Freedom from Liquid Leakage
Force at Break
Simulated Use
Guidewire Passage
Accelerated Aging

**H. Biocompatibility:**

Testing for all materials used has been tested in accordance with ISO 10993. All biocompatibility testing demonstrates the materials used meet the requirements of ISO 10993.

**I. Technological Characteristics:**

Technological similarities between the proposed devices and predicate devices remain the same.

**J. Safety and Performance Tests**

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, design verification testing was performed according to protocols based on the recommendations/requirements of applicable FDA guidance and FDA recognized international standards. Verification testing, determined to be applicable to the safety and efficacy of the device, was shown to meet predetermined acceptance criteria listed therein.

Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with an internal protocol based on ISO 14971:2000, *Medical Devices – Risk Management for Medical Devices*. The analysis did not identify any new types of safety or efficacy questions for the subject Over the Needle Tearaway with Flared Hub device.

**K. Summary of Substantial Equivalence:**

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

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Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 15, 2013

Medical Components Inc.
C/O Jessica Leo
Regulatory Associate
1499 Delp Drive
Harletsville, PA 19438

Re: K130687
Trade/Device Name: 2F and 3F Vascu-Sheath Tearaway Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: July 3, 2013
Received: July 3, 2013

Dear Ms. Leo,

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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. 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 -S

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

# Indications for Use

510(k) Number (if known): K130687

Device Name: ___Medcomp® Vascu-Sheath Tearaway Introducer _____

Indications for Use:

The 2F and 3F Vascu-Sheath Tearaway Introducer is intended for percutaneous venous access by modified Seldinger Technique in neonates, infants, and children.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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