K090394

510(k) SUMMARY

SEP - 1 2009

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Jean Callow Regulatory Specialist
Date Prepared:	February 16, 2009

B. Trade Name: Valved Tearaway Introducer

Common Name:	Introducer, Catheter
Classification:	DYB
C.F.R. Section:	870.1340

C. Predicate Device:

K040150 MedAmicus FlowGuard™ Peelable Introducer
K053092 Medcomp Vascu-Sheath® II Introducer Set

D. Device Description:

The Medcomp Valved Tearaway Introducer is a two-part single use device used to obtain vascular access and facilitate intravascular catheter insertion. The Medcomp Valved Tearaway Introducer consists of a peel-able introducer sheath which contains a "duckbill" seal to substantially minimize air/blood from entering or escaping when the dilator is removed. The dilator is comprised of a cylindrical tube with a locking hub; the sheath is also a cylindrical tube with a hub and valve. When the dilator is fully seated it snaps into the hub of the introducer sheath to prevent independent movement of either piece when in use. The dilator extends beyond the sheath to provide a zero tolerance clearance between sheath and dilator. The sheath and dilator when used in conjunction with an introducer needle and guidewire provide a means to obtain a percutaneous opening to the vascular system to facilitate the insertion of a catheter. After removing the dilator a catheter can then be placed through the sheath. Breaking the sheath's hub and peeling the sheath away from the catheter then allows the sheath to be removed. The dilator is composed of a High Density Polyethylene with Barium Sulfate for visibility under fluoroscopy by the attending physician during insertion. The sheath is composed of PTFE to provide a smooth, consistent peel.

E. Intended Use:

The Valved Tearaway Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.

F. Comparison to Predicate Device:

The technological characteristics of the Valved Tearaway Introducers are substantially equivalent to the predicate devices in terms of intended use, design, material type, performance, and method of sterilization.

G. Performance Data:

In Vitro performance data for the Medcomp Valved Tearaway Introducer, including peel force, demonstrates that this device is substantially equivalent to the legally marketed devices.

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.

H. Biocompatibility:

Biocompatibility testing demonstrates that the materials used meets the requirements of ISO 10993 for an external communicating device with limited duration blood path contact.

I. Conclusion:

The Valved Tearaway Introducers have equivalent indications for use as the predicate devices. The bench testing and biocompatibility testing contained in our submission demonstrates that there are no differences in technological characteristics which would raise any new issues of safety or effectiveness. Thus, the Valved Tearaway Introducers are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

MEDCOMP®
% Ms. Jean Callow
Regulatory Specialist
1499 Delp Drive
Harleysville, PA 19438

SEP 1 2009

Re: K090394
Trade/Device Name: Valved Tearaway Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: August 20, 2009
Received: August 21, 2009

Dear Ms. Callow:

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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram R. Zuckerman

Bram 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): K090394

Device Name: Valved Tearaway Introducer

Indications for Use:

THE VALVED TEARAWAY INTRODUCERS ARE INTENDED TO OBTAIN CENTRAL VENOUS ACCESS TO FACILITATE CATHETER INSERTION 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-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

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