K 030270

510(k) SUMMARY

APR 11 2003

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-0818 Fax
Contact:	Meghan J. Tintle Regulatory Affairs Assistant
Date Prepared:	January 23, 2003

B. Trade Name: Medcomp Silicone Vascu-PICC™

Common Name: Catheter, Intravascular, Therapeutic, Long-Term

Classification: LJS

C.F.R. Section: 880.5970

C. Predicate Device: A137605 Cook PICC Catheters

D. Device Description:

The Medcomp Silicone Vascu-PICC™ Catheters are designed for peripheral vein catheterization. The Silicone Vascu-PICC™ lumen is comprised of a soft radiopaque silicone material. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration.

The catheters are available in 3F, 4F, and 5F single lumen versions, and 4F, 5F, and 6F double lumen versions. All versions are 60 cm long with depth markings in 5cm increments.

The Silicone Vascu-PICC™ Catheter product line is packaged with the necessary accessories to facilitate catheter insertion.

E. Intended Use:

The Medcomp Silicone Vascu-PICC™ Catheters are designed for long-term central venous catheterization or prolonged intravenous administration of fluids, medications, and/or when nutritional therapy is prescribed.

This catheter may be inserted via the basilic or cephalic vein.

F. Comparison to Predicate Device:

The Medcomp Silicone Vascu-PICC™ Catheter is substantially equivalent to the predicate device in terms of intended use, insertion method, anatomical location,

design, material type, performance, labeling, manufacturing process, and method of sterilization.

G. Performance Data:

In vitro testing was performed on the Medcomp Silicone Vascu-PICC™ Catheter to assure reliable design and performance in accordance with ISO 10555-1 and 10555-3.

Biocompatibility testing on the Medcomp Silicone Vascu-PICC™ Catheter demonstrates that the materials used meet the requirements of ISO 10993 for a permanent contact device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2003

Ms. Meghan J. Tintle
Regulatory Affairs Assistant
MEDCOMP®
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K030270
Trade/Device Name: MEDCOMP SILICONE Vascu-PICC™ CATHETER
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: January 23, 2003
Received: January 27, 2003

Dear Ms. Tintle:

This letter corrects our substantially equivalent letter of January 23, 2003 regarding the contact name.

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 (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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K030270

Device Name: MEDCOMP SILICONE Vascu-PICC™CATHETER

Indications for use:

THE MEDCOMP SILICONE Vascu-PICC™ CATHETERS ARE DESIGNED FOR LONG-TERM CENTRAL VENOUS CATHETERIZATION OR PROLONGED INTRAVENOUS ADMINISTRATION OF FLUIDS, MEDICATION, AND /OR WHEN NUTRITIONAL THERAPY IS PRESCRIBED.

THIS CATHETER MAY BE INSERTED VIA THE BASILIC OR CEPHALIC VEIN.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucenta
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K030270