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510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-1787 Fax
Contact:	Jeanne M. Cush
Date Prepared:	October 29, 1999

B. Trade Name: Medcomp Hemo-Flow Catheter
Common Name: Hemodialysis Catheter, Implanted
Classification: 78 MSD
C.F.R. Section: 876.5540

C. Predicate Device: K972207 Medcomp Ash Split-Cath

D. Device Description:

The Medcomp Hemo-Flow Catheter is a polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. Both lumens are "D" shaped, open at the distal tip, with two side holes. The distal venous lumen is tapered and extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long term placement.

The lumens are connected to the extensions via a soft pliable hub with suture wing. The arterial and venous extensions are identified by red and blue luer connectors and clamps. Priming volume information is printed on the extensions for ease in identification.

E. Intended Use:

The Medcomp Hemo-Flow Catheter in indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site is the subclavian vein as required.

F. Comparison to Predicate Device:

The technological characteristics of the Hemo-Flow are substantially equivalent to the predicate in terms of intended use, insertion method, anatomical location, design, performance, labeling, manufacturing process and method of sterilization.

The difference between these devices is the material formulation and the Ash Split-Cath lumens are intended to be split prior to insertion.

G. Performance Data:

In Vitro performance data for the Medcomp Hemo-Flow, including tensile strength, joint strength, leakage, recirculation and flow performance demonstrate that this device is substantially equivalent to legally marketed devices intended for hemodialysis and apheresis treatments.

Biocompatibility testing on the Hemo-Flow Catheters demonstrates 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

OCT - 3 2001

Ms. Jeanne M. Cush
Technical Submissions Coordinator
Medical Components, Inc.
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K994105
MedComp® Hemo-Flow Double Lumen Catheter, Models HFS-24, HFS-28, HFS-32, HFS-36 and HFS-40
Dated: December 6, 1999
Received: December 6, 1999
Regulatory Class: III
21 CFR §876.5540/Procode: 78 MSD

Dear Ms. Cush:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number:

Device Name: Medcomp Hemo-Flow Double Lumen Catheter

Indications for use:

The Medcomp Hemo-Flow Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site includes the subclavian vein as required.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994105

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

(Optional Format 1-2-96)