

K991320  
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NOV 10 1999

## 510(k) Summary

**SUBMITTER:****Submitted by:**

<b>Company Name:</b>	MedComp
<b>Address:</b>	1499 Delp Drive Harleysville, PA 19438
<b>Telephone:</b>	215-256-4201
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**CONTACT PERSON:** Jeanne Cush**DATE SUMMARY PREPARED:** April 5, 1999 / REVISED October 29, 1999

**TRADE NAME:** MedComp® DUO-COAT Catheter Double Lumen  
**COMMON NAME:** Hemodialysis Catheter, Non-Implanted

**SUBSTANTIALLY EQUIVALENT TO:** Duo-Flow Double Lumen Catheter K974236**DESCRIPTION of the DEVICE:**

The MedComp® DUO-COAT Catheter Double Lumen combines the MEDCOMP Duo-Flow Catheter with a dual purpose surface coating. Bound heparin reduces thrombus formation on the catheter outer surface and at arterial and venous ports, in 4-hour invitro-studies<sup>1</sup>. The round catheter design and lubricious surface may aid in catheter insertion by reducing friction on the outer surface. The fixed circular tube within a tube allows for a 360 arterial uptake and provides consistent flows from 350 to 400 ml/min. The catheter lumen is fabricated from a soft, thermo-sensitive, polyurethane material that is rigid upon insertion, but which becomes soft upon reaching body temperature to reduce vessel trauma. The external lumen surface incorporates heparin to reduce the risk of thrombus. The catheter hub is molded from soft pliable polyurethane to increase patient comfort. The soft radiopaque tip reduces vessel trauma and aids in confirmation of tip placement. Extensions are color coded with a red luer and clamp for the arterial lumen and a blue luer and clamp for the venous lumen for easy identification.

**INDICATIONS FOR USE:**

The MedComp® Duo-Coat Catheter is indicated for use in attaining short 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 sites are the subclavian or femoral vein.

**SAFETY and EFFECTIVENESS :**

Testing conducted on the uncoated catheter, similar to that conducted on the predicate device (including biocompatibility screens and mechanical integrity) confirmed that the presence of the lubricious heparin did not affect the safety of the catheter. Comparison of treated and untreated surfaces showed a marked reduction in drag on the surface after application of the lubricious heparin. Hemodynamic testing under strenuous simulation testing demonstrated that the surface modification reduced the risk of thrombosis.

<sup>1</sup> Results from comparative evaluation against uncoated control catheters after simulated dialysis testing with heparinized bovine blood.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 10 1999

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

Re: K991320  
Trade Name: Medcomp® Duo-Coat Catheter, Double Lumen  
Regulatory Class: II  
21 CFR §876.5540/Product Code: 78 MPB  
Dated: August 13, 1999  
Received: August 16, 1999

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.

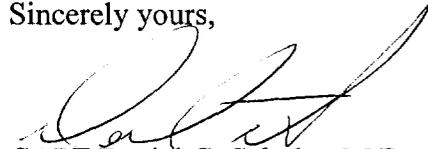
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

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result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. 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

# INDICATIONS FOR USE

510(k) Number: K991320

Device Name: Medcomp Duo-Coat Double Lumen Catheter

Indications for use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
 (Per 21 CFR 801.109)

OR

Over-The-Counter

(Optional Format 1-2-96)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K991320/5<sup>001</sup>