K022570

OCT 31 2002

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-1787 Fax
Contact:	Florence A. Caikoski
Date Prepared:	October 30, 2002

B. Trade Name: Medcomp Repair Kit
Common Name: Kit, Repair, Catheter, Hemodialysis
Classification: NFK
C.F.R. Section: 876.5540

C. Predicate Device: K011015 Bard Catheter Repair Kit

D. Device Description:

The Medcomp Repair Kit is two-piece replacement luer adaptor and cap used to repair damaged female luer connectors on Medcomp Hemodialysis Catheters. The Medcomp Repair Kit also consists of replacement arterial and venous clamps.

E. Intended Use:

The Medcomp Repair Kit is indicated for use in replacing damaged female luer connectors, clamps, or repairing extensions where there is a minimum of 4.5cm viable extension tubing.

Repairs Medcomp Catheters: 10F Ash Split Cath® XL, 10F Ash Split Cath® II, 14F Ash Split Cath®, 14F Ash Split Cath® XL, 14F Ash Split Cath® II, 16F Ash Split Cath® II

F. Comparison to Predicate Device:

The technological characteristics of the Medcomp Repair Kit are substantially equivalent to the predicate device in terms of intended use, design, material type, performance, and method of sterilization.

G. Performance Data:

In-Vitro performance data for the Medcomp Repair Kit including simulated use, tensile strength and leakage demonstrates that this device is substantially equivalent to legally marketed device.

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
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2002

Ms. Florence A. Caikoski
Regulatory Affairs Associate
MEDCOMP
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K022570
Trade/Device Name: MEDCOMP Repair Kit, Model # ASPCRPK, for repairing 10F and 14F Ash Split Cath® XL; 14F Ash Split Cath®; and 10F, 14F and 16F Ash Split Cath® II
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NFK
Dated: July 31, 2002
Received: August 2, 2002

Dear Ms. Caikoski:

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). 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 (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 (21 CFR Part 807); 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 begin 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 the 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-__. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

David C. Degerman

for Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K022570

Device Name: MEDCOMP REPAIR KIT

Indications for use:

THE MEDCOMP REPAIR KIT IS INDICATED FOR USE IN REPLACING DAMAGED FEMALE LUER CONNECTORS, CLAMPS, OR REPAIRING EXTENSIONS WHERE THERE IS A MINIMUM OF 4.5cm VIABLE EXTENSION TUBING.

REPAIRS MEDCOMP CATHETERS: 10F Ash Split Cath® XL, 10F Ash Split Cath® II, 14F Ash Split Cath®, 14F Ash Split Cath® XL, 14F Ash Split Cath® II, 16F Ash Split Cath® II

(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)

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022570