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SECTION H

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510(k) SUMMARY

This section contains a summary of safety and effectiveness for the Mahurkar 13.5 Fr Cuffed Catheter with curved extensions as defined in 21 CFR 807.3 and required by 21 CFR 807.92.

(1) *Submitter's name, address, telephone number, contact person, date of preparation:*

Sherwood Medical Company  
3303 Monte Villa Parkway  
Bothell, WA 98021-8906  
phone: 425.398.4178  
FAX: 425.402.2017

Contact person: Laurie Powers Senior Regulatory Compliance Specialist, Regulatory Affairs  
Date summary was prepared: 14 April 1998

(2) *Name of the device:*

Trade Name - Mahurkar 13.5 Fr Cuffed Catheter with Curved Extensions  
Common Names - Hemodialysis Catheter, Apheresis Catheter, Intravascular Catheter  
Classification Names -  
21 CFR 876.5540 - Non-Implanted Blood Access Devices and Accessories  
21 CFR 880.5200 - Intravascular Catheter

(3) *Identification of predicate device:*

PermCath Dual Lumen Catheters (Quinton Instrument Co., Bothell, WA)

(4) *Description of the device:*

The Mahurkar 13.5 Fr Cuffed Catheter with curved extensions is a radiopaque silicone tube with two D-shaped lumina. The lumina can be distinguished by the color-coded luer-lock adapters on the clear silicone rubber extensions: the red adapter indicates the proximal lumen, and the blue adapter indicates the distal lumen. During hemodialysis and apheresis, the proximal lumen provides "arterial" outflow from the patient and the distal lumen provides "venous" return.

The Mahurkar 13.5 Fr Cuffed Catheter with curved extensions is available in four (4) implantable lengths (36 cm, 40 cm, 45 cm, and 50 cm), and will be packaged in single, catheter kit and catheter tray configurations.

(5) *Intended use of the device:*

The Mahurkar 13.5 Fr Cuffed Catheter with curved extensions is intended to be used as an acute or chronic central venous access device for hemodialysis, apheresis, and infusion.

(6) *Comparison to predicate device:*

The technological characteristics of the Mahurkar 13.5 Fr Cuffed Catheter with curved extensions, including catheter type, intended use, insertion method, anatomical placement of catheter tip, number of lumens, and materials are similar to that of the predicate device identified in paragraph

(3) of this Summary. The unique characteristic for the Mahurkar 13.5 Fr Cuffed Catheter described in this submission is the curved extensions.

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(7) *Performance data:*

Performance data for the Mahurkar 13.5 Fr Cuffed Catheter with curved extensions were compared to that of the predicate device identified in paragraph (3) of this Summary. These test results demonstrate that the device is substantially equivalent to the predicate device commercially distributed for hemodialysis, apheresis, and infusion.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Laurie Powers  
Senior Regulatory Compliance Specialist  
Sherwood Medical Company  
3303 Monte Villa Parkway  
Bothell, Washington 98021

Re: K981365  
Mahurkar 13.5 Cuffed Catheter with Curved Extensions  
Regulatory Class: III  
21 CFR 876.5540/Product Code: 78 MSD  
Dated: September 14, 1998  
Received: September 15, 1998

Dear Ms. Powers:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of 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 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, 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 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 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

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have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

In addition, we have determined that your device kit contains PVP iodine ointment, 1% lidocaine, and povidone iodine swabsticks which are subject to regulation as drugs.

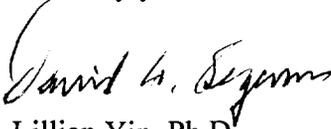
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857  
(301) 594-0101

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 our labeling regulation (21 CFR Part 801 and additionally 809 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,

  
for

Lillian Yin, Ph.D.  
Director, Division of Reproductive, Abdominal,  
Ear, Nose and Throat, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K981365

Device Name: Mahurkar 13.5 Fr Cuffed Catheter with Curved Extensions

Indications for Use:

The Mahurkar 13.5 Fr Cuffed Silicone catheter is designed for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter  
Use \_\_\_\_\_

(Per 21 CFR 801.109)

\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K981365

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