K961392

510 (k) Summary

Company: Sil-Med Corporation
700 Warner Boulevard
Taunton, MA 02780

JUL 18 1997

Telephone: (508) 823-7701
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Contact Person: Karen K. Sylvia
QA/QC Manager

Trade Name: ***Peritoneal Dialysis Coil Catheter with Spi-Argent™II***

Common Name: Peritoneal Dialysis Catheter

Classification Name: 78 FJS Peritoneal dialysis system and accessories. (878.5630)

Description: Peritoneal Dialysis Coil Catheter with Spi-Argent™II, for the transport of dialysate solution to and from the peritoneal cavity for treatment of renal failure; suitable for CAPD (Continuous Ambulatory Peritoneal Dialysis).

Predicate Device: Peritoneal Dialysis Coil Catheter: K850247
Mediastinal Silicone Drain: K942709
Antimicrobial Multi-Lumen Central Venous Catheter: K900263

Intended Use: Peritoneal Dialysis Coil Catheter with Spi-Argent™II, for the transport of dialysate solution to and from the peritoneal cavity for treatment of renal failure; suitable for CAPD (Continuous Ambulatory Peritoneal Dialysis).

Peritoneal Dialysis Coil Catheter with Spi-Argent™II is the same as the Peritoneal Dialysis Coil Catheter, K850247 except for the Spi-Argent™II option offering. Spi-Argent™II is the same surface treatment as the K942709, Mediastinal Drain with Spi-Argent™II. The Spi-Argent™II surface treatment provides a lubricious surface to ease insertion and removal of the catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 1997

Ms. Karen K. Sylvia
QA/QC Manager
Sil-Med Corporation
700 Warner Boulevard
Taunton, Massachusetts 02780

Re: K961392
Peritoneal Dialysis Coil Catheter
with Spi-Argent™ II
Dated: May 1, 1997
Received: May 2, 1997
Regulatory class: II
21 CFR §876.5630/Product code: 78 FJS

Dear Ms. Sylvia:

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 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. 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 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 requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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/dsmamain.html.

Sincerely yours,

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

Sil-Med Corporation
700 Warner Boulevard
Taunton, MA 02780
Revision Date: 14 April, 1997

510(k) Number (if known): K961392
Device Name: ***Peritoneal Dialysis Coil Catheter with Spi-Argent™II***

Indications For Use:

Peritoneal Dialysis Catheter with Spi-Argent™II surface treatment, for the transport of dialysate solution to and from the peritoneal cavity for treatment of renal failure; suitable for CAPD (Continuous Ambulatory Peritoneal Dialysis)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Gatting
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K961392

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

(Optional Format 1-2-96)