K972521

OCT - 1 1997

510 (k) Summary

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

Telephone: (508) 823-7701
Fax: (508) 823-1438

Contact Person: Karen K. Sylvia
QA/QC Manager

Trade Name: Navigator
Common Name: Stylet
Classification Name: Introduction/drainage catheter and accessories accessory intended to aid in the manipulation of or insertion of the device into the body. (878.4200)
Description: Stainless steel wire rod intended to aid in the manipulation of or insertion of the catheter for placement in the peritoneum.
Predicate Device: Accurate Surgical's Insertion Stylet
Medigroup's Catheter Stylettes
Quinton's Stylet
Intended Use: The Navigator (stylet) is a stainless steel wire rod, inserted into the catheter to assist with insertion and placement of the catheter in the peritoneum.

Biocompatability Testing:

Test	Results
Cytotoxicity Study	Pass
Hemolysis Study - In Vitro	Non-Hemolytic

Sil-Med Corporation's Navigator (stylet) is dimensionally equivalent to Quinton's stylet and equivalent to offerings by Accurate Surgical and Medigroup. The intended use of all stylets are the same. The Navigator is manufactured from stainless steel as are the predicate stylets. The Navigator will be sold double pouched and sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT - 1 1997

Re: K972521
Trade Name: Navigator
Regulatory Class: I
Product Code: GAH
Dated: July 3, 1997
Received: July 7, 1997

Dear Ms. Sylvia:

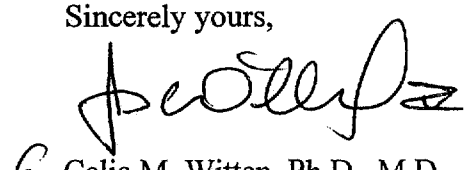
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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, 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) 594-4595. 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,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sil-Med Corporation
700 Warner Boulevard
Taunton, MA 02780
Date: 3 July, 1997

510(k) Number (if known): K972521
Device Name: Navigator (stylet)

Indications For Use:

The Navigator (stylet) is a stainless steel wire rod, inserted into the catheter to assist with insertion and placement of the catheter in the peritoneum.

(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 General Restorative Devices
510(k) Number K972521

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)