



JUN 9 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Neil J. Rasmussen  
President  
DaySpring Medical, Inc.  
1936 Beacon Court  
Boulder, CO 80302Re: K991003  
Pump Segment Rinse Lines  
and T-Connectors  
Dated: March 25, 1999  
Received: March 25, 1999  
Regulatory Class: II  
21 CFR §876.5820/Procode: 78 FKY

Dear Mr. Rasmussen:

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. 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) 594-4613. 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/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

510(k) Number: K991003

Device Name: Pump Segment Rinse Lines & T-Connectors

Pump segment rinse line w/ slip-on connector (Our Catalog No. PS100R)  
Pump segment rinse line w/ luer-lock connector (Our Catalog No. PS100B)

T-connector, short, w/ slip-on connector (Our Catalog No. ST100R)  
T-connector, short, w/ luer-lock connector (Our Catalog No. ST100B)  
T-connector, long, w/ slip-on connector (Our Catalog No. LT100R)  
T-connector, long, w/ luer-lock connector (Our Catalog No. LT100B)

Indications for Use:

The rinse lines are used to connect one blood port of a dialyzer to the opposite blood port to create a loop. When both blood ports are so connected, the line itself is connected to a pump on a rinse machine which primes the dialyzer with rinse solution and fills it with a sterilant solution, so the dialyzer can be disinfected, while it is stored on the shelf awaiting its next use. The rinse line is also used for taking a sample of the sterilant solution. This is done by inserting a needle through an access site on the rinse line, and taking a sample for testing. The devices are clean, but not sterile.

The t-connectors are used during the rinse procedure of the dialyzer. They connect each end of the two blood ports on a dialyzer to the reprocessing system and allow cleaning solutions to be passed through the membrane of the dialyzer. The devices are clean, but not sterile.

The connecting ends of the rinse lines and the t-connectors are of two possible types: a slip-on connector or a luer-lock, screw-on connector.

The slip-on connector is tapered to securely adhere to the "male" end of the blood port. It is released by pulling it straight off. The surface of the blood port and the surface of the slip-on connector meet, and create a friction seal that prevents any fluids from leaking out of the dialyzer.

The luer-lock, screw-on connector securely screws on to the "male" end of the blood port. It is released by unscrewing it. The surface of the blood port and the surface of the luer-lock, screw-on connector meet, and create a friction seal that prevents any fluids from leaking out of the dialyzer.

*prescription* ✓



*Over-the-Counter* —

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

510(k) Number K991003