



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 22 1999

Mr. Neil J. Rasmussen  
President  
Dayspring Medical, Inc.  
1936 Beacon Court  
Boulder, CO 80302

Re: K991005  
Vented dialysate port cap  
Dated: March 25, 1999  
Received: March 25, 1999  
Regulatory Class: II  
21 CFR §876.5820/Procode: 78 LLB

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: K991005

Device Name: Vented dialysate port cap (Our Catalog No. DPC101VS)

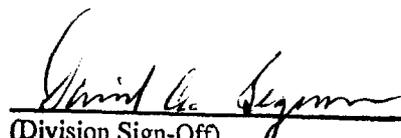
Indications for Use:

The devices are used for capping off the two dialysate port access ends of a hollow fiber dialyzer. The devices are used by technicians in a dialysis unit during the cleaning, reprocessing, and disinfecting of the dialyzer. During the disinfecting procedure, the technician fills the dialyzer with a sterilant solution that sterilizes the inner filter membrane of the dialyzer. The dialysate port caps prevent the large-scale leakage of fluid stored inside the dialyzer. The vented dialysate port caps, in the process of venting pressure, may leak a very small amount of fluid. The device replaces the original equipment manufacturer's closure ports after the initial use of the dialyzer. The devices are clean, but not sterile.

The inside opening of the caps are tapered to match the standard dialysate ports found on hollow fiber dialyzers. The devices mate directly to the dialysate port. The caps are affixed by placing the open end of the cap over the "male" end of the dialysate ports. They are released by pulling them straight off. The surface of the dialysate port and the surface of the dialysate port cap device meet, and create a friction seal that prevents stored fluids from leaking out of the dialyzer. The vented dialysate port cap has a pop-up piece at the top of the device. These vented caps are specifically for use with a sterilant solution known as Renalin, and manufactured by Minntech Corp. This sterilant is known to create pressure inside the dialyzer. The vented cap is a device to relieve this pressure buildup.

Prescription

Over-The-Counter

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K991005