K062112

510(K) SUMMARY
(as required by 807.92(c))

JUN - 4 2007

Submitter of 510(k): **SunMed**
12393 Belcher Road, #450
Largo, FL 33773 USA

Phone: 800-433-2797
Fax: 800-671-7988

Contact Person: Barry Wall

Date of Summary: May 10, 2006

Trade/Proprietary Name: SunMed Foley Catheter

Classification Name: Catheter, retention type, balloon

Product Code: **EZL**

Intended Use: The SunMed Foley Catheter is used to drain fluids to and from the urinary tract.

Product Description:

The catheters are comprised of a 2 lumen shaft with proximal funnel, inflation valve and distal retaining balloon. One lumen is for draining fuleds to and from the urinary tract. The second lumen is to inflate and deflate the balloon. On models with a third lumen, it is used in conjunction with the first lumen for flushing the urinary tract. The balloon fill volumes in ml and shaft size in French Gauge (Fr), Charriere (Ch) or millimeter (mm) are indicated on the funnel of each individual cathter and the distal tip type can be indicated on the individual pack label and / or outer carton. Sizes range from 6 to 30 Ch / Fr.

Predicate Device: Rusch Silicon Coated Foley Catheter – K980870

Substantial Equivalence:

SunMed claims the proposed device to be substantially equivalent to the device previously cleared by FDA in K980870. SunMed claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical, operational and biological specification as compared to the predicate devices. A description of the similarities and differences is located in Section 9 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 4 2007

SunMed, Inc.
c/o Mr. Arthur J. Ward
AJW Technology Consultants, Inc.
962 Allegro Lane
APOLLO BEACH FL 33572

Re: K062112
Trade/Device Name: SunMed Foley Catheters
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: May 23, 2007
Received: May 29, 2007

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K062112

Indications for Use

510(k) Number (if known): K062112

Device Name: SunMed Foley Catheter

Indications for Use:

The SunMed Foley Catheter is used to drain fluids to and from the urinary tract.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062112