K062240

510(k) Summary

General Information

OCT 16 2006

Classification	Class II
Trade Name	CareVent
Submitter	Chief Medical LLC P.O. Box 772 105 Pioneer Lane Teton Village, WY. 83025
Contact	Scott Horn President

Intended Use

The CareVent is intended for use with a Foley Urinary Catheter for the management of urinary drainage.

Predicate Devices

K041983	Option-vm Urinary Catheter Opticon Medical, Inc.
K051059	AMSURE 100% Silicone Foley Catheter Amsino International, Inc.

Device Description

The CareVent device is used with a Foley catheter for the management of urinary drainage. The CareVent offers the physician/user a means to temporarily control the flow of urine from the bladder. Temporary control of urine may be desired for bladder conditioning, diagnostic procedures or patient comfort. The CareVent valve is easily inserted into the distal end of a Foley catheter and may be left open for

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continuous drainage or manually operated for temporarily closure. The device is provided sterile and for single patient use.

Materials

All materials used in the manufacture of the CareVent are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included general operation, valve operation, and fluid leak. All testing was successful.

Summary of Substantial Equivalence

The CareVent is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 16 2006

Chief Medical Devices, LLC
c/o Mr. Scott D. Horn
P.O. Box 772
105 Pioneer Lane
TETON VILLAGE WY 83025

Re: K062240
Trade/Device Name: CareVent
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: July 26, 2006
Received: August 2, 2006

Dear Mr. Horn:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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

K062240

Indications for Use

510(k) Number (if known):	This application K062240
Device Name:	CareVent
Indications for Use:	The CareVent is intended for use with a Foley Urinary Catheter for the management of urinary drainage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use _ OR (Per 21 CFR 801.109)

Over-The-Counter Use (Optional Format 1-2-96)

David G. Hyman

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