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K033830

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# 510(k) SUMMARY

## OPTICON MEDICAL

## OPTION-*vf*™ Urinary Catheter with Adaptor

**Submitter's Name and Contact Information**

Opticon Medical
7001 Post Road, Suite 100
Dublin, OH 43016

Primary Contact: Glenn D. Brunner, President
Phone Number: (614) 366-2000
Fax Number: (614) 336-2059

Date Prepared: December 08, 2002

## Device Name

Trade / Proprietary Name: OPTION-*vf*™ Urinary Catheter with Adaptor

Common / Usual Name: urinary catheter or Foley catheter

Classification Name: catheter, retention type, balloon (product code EZL; 21 CFR 876.5130)

## Predicate Device

- K023090, OPTION-*vf*™ Urinary Catheter
- K760093, Bardex® Silicone Foley Catheter
- BARD® Adaptor and Tubing

## Intended Use

The OPTION-*vf* is intended to provide drainage of the urinary bladder.

The OPTION-*vf* is indicated for use only for urinary bladder drainage in female patients: 1) who have acute conditions that require short-term (14 days or less) urinary management; 2) who are capable of operating the device in accordance with its instructions for use; and 3) for whom normal bladder cycling is not contraindicated.

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## Device Description

The OPTION-*vf* is an indwelling catheter that provides drainage of the urinary bladder. It is a sterile, single-use, disposable device that is to be prescribed by a physician and inserted and removed by an appropriate health care professional. The device is composed of biocompatible silicone elastomers, and consists of: a flexible shaft with two opposing eyelets in the proximal tip for urine entry, one internal lumen for urine drainage and a second lumen for balloon inflation; a retention balloon; an adjustable retainer ring; a self-sealing balloon inflation microvalve port; and a urine discharge bulb with integral valve. The catheter may be used with the Continuous Drainage Adaptor accessory to provide continuous urinary drainage.

## Comparison to Predicate Device

The OPTION-*vf* catheter incorporates a normally closed discharge valve housed within the discharge bulb (see Figure 1 of the IFU). When used without the Continuous Drainage Adaptor as previously cleared (OPTION-*vf*™ Urinary catheter), urine drainage occurs upon manual actuation of the discharge bulb, thus opening the valve. When the OPTION-*vf* catheter is used in conjunction with the Continuous Drainage Adaptor accessory according to the Instructions for Use, the adaptor simply holds the valve open for continuous drainage, making the catheter substantially equivalent to typical continuous drainage Foley catheters including its original predicate device (C.R. Bard, Inc. Bardex® Silicone Foley Catheter).

## Supporting Information

A risk analysis for the OPTION-*vf* with adaptor and the verification test results reported in this 510(k) application substantiate equivalence to the predicate devices. Thus, the OPTION-*vf* and Continuous Drainage Adaptor do not raise any new questions of safety or efficacy.

## Conclusion

The OPTION-*vf* urinary catheter with adaptor is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2004

Opticon Medical
c/o Gerard J. Prud'homme, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
WASHINGTON DC 20004

Re: K033830
Trade/Device Name: OPTION-*vf*™ Urinary Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZL
Regulation Number: 21 CFR §876.5250
Regulation Name: Urine collector and accessories
Regulatory Class: Class II Exempt
Product Code: 78 KNX
Dated: December 9, 2003
Received: December 10, 2003

Dear Mr. Prud'homme:

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 (PMA), it may be subject to 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 the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

# Indications for Use

510(k) Number (if known): K033830

Device Name: OPTION-*vf*™ Urinary Catheter with Adaptor

Indications For Use: The OPTION-*vf* is indicated for use only for urinary bladder drainage in female patients: 1) who have acute conditions that require short-term (14 days or less) urinary management; 2) who are capable of operating the device in accordance with its instructions for use; and 3) for whom normal bladder cycling is not contraindicated.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033830