

510(k) SUMMARY

OPTICON MEDICAL, INC.

OPTION-*vf*TM Urinary Catheter

Submitter's Name and Contact Information

Opticon Medical, Inc.
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: September 13, 2002

Device Name

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

Common / Usual Name: urinary catheter or Foley catheter

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

Predicate Devices

- K961697, Medical Device International, Inc. Opticon Female Urinary Catheter for Continuous Drainage ("Opticon Direct").
- K760093, C.R. Bard, Inc. Bardex® Silicone Foley Catheter ("Bardex").

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.

Technological Characteristics and Substantial Equivalence

Device Description:

The OPTION-*vf* is an indwelling catheter that provides controlled 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 device is inserted through the urethra to position the proximal tip and balloon into the urinary bladder. Once the catheter is properly inserted, the teardrop-shaped balloon is inflated with 5 to 10 cc of sterile water through the microvalve port via a standard syringe and a blunt cannula. The retainer ring is then adjusted to the urinary meatus, thus gently anchoring the device in place. Removal of the OPTION-*vf* follows aspiration of the fluid from the balloon.

The patient-operated discharge valve within the OPTION-*vf* is housed within the discharge bulb. When the bulb is squeezed, the valve opens allowing urine to pass. When the bulb is released, the valve closes, providing the patient with direct control over urinary drainage. The OPTION-*vf* thus allows the patient to mimic normal voiding and permits patient mobility and comfort by eliminating the need for urine collection bags and tubing.

Substantial Equivalence Comparison:

The OPTION-*vf* and the predicate devices are all indwelling urinary catheters, which are used in the same anatomic location for the same purpose. The OPTION-*vf* is similar in design, materials of construction, physical dimensions, methods of insertion, maintenance, and removal, etc. to the predicate catheters. It also follows equivalent principles of operation, with the exception that the predicate catheters continuously drain into a urine collection bag, whereas the OPTION-*vf* has an integral valve that allows the user to control bladder drainage.

The OPTION-*vf* is substantially equivalent to the other legally marketed catheters referenced above. The OPTION-*vf* and the predicate devices are all indwelling urinary catheters used to drain the urinary bladder, thus the OPTION-*vf* raises no new issues of safety or effectiveness.

Device Performance

The company has completed both the engineering testing typically required for clearance of a standard Foley catheter, and sufficient laboratory and clinical performance testing to demonstrate the comparative safety and effectiveness of the OPTION-*vf*.

Engineering Testing:

Engineering verification testing confirms that results obtained from bench testing according to the recognized Foley standard; ASTM F 623-99, Standard Performance Specification for Foley Catheter, as well as additional verification testing demonstrate conformance of the OPTION-*vf* device with clinical and design requirements. The device conforms to all

applicable elements of the ASTM Foley catheter standard, and demonstrates proper performance in all valve-related testing.

Clinical Testing:

In a multi-center randomized controlled clinical trial, female patients requiring short-term urinary catheterization were treated with either a standard Foley indwelling catheter or the experimental Opticon-*vf*TM catheter.

There was no significant difference between groups with respect to the incidence of significant bacteriuria following catheter removal. The mean residual bladder volume at the time of catheter removal was also comparable between groups.

A review of adverse events by treatment group showed that adverse event rates were similar between the groups. In general, adverse events associated with the Opticon catheter were of mild severity and were resolved quickly either with appropriate patient counseling or catheter removal.

Results from the patient questionnaire revealed significant benefits of the Opticon catheter as compared to the Foley catheter with respect to mobility, pain/discomfort, self-consciousness, sleep disruption, and ability to shower or get dressed. These benefits follow directly from the design of the Opticon catheter in which bulky urine collection bags and connecting tubes are eliminated, as is the need to periodically empty the urine collection bag. Moreover, patients are able to maintain a more normal urinary function, with normal bladder cycling as compared to a continuously contracted bladder with constant drainage, and with the ability to discretely drain the bladder when desired.

In all instances, the OPTION-*vf* functioned to provide drainage of the urinary bladder and the device performance was as expected.



MAR 19 2003

Mr. Glenn D. Brunner
President
Opticon Medical, Inc.
7001 Post Road
Suite 100
DUBLIN OH 43016

Re: K023090

Trade/Device Name: OPTION-*vf*TM Urinary Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZL
Dated: December 23, 2002
Received: December 24, 2002

Dear Mr. Brunner:

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 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:

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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indication for Use

510(k) Number: K023090

Device Name: OPTION-*vf*TM Urinary Catheter

Indication 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

David A. Johnson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K023090