K990509

MAY 18 1999

510(k) SUMMARY
[Refer to 21 CFR §807.92]

Submitted by:	Implemed, Inc. 313 Pleasant Street Watertown, MA 02472 (617) 923-6375
Contact Person:	Anthony L. Blank
Date Prepared:	May 13, 1999
Proprietary Name:	OLIGON™ FOLEY CATHETER
Common Name:	Uninary Drainage Catheter (Foley)
Classification Name:	urological catheter, retention type, balloon (78 EZL); Class II as described in 21 CFR 876.5130 (b)
Predicate Device:	Kendall 100% Silicone Foley Catheter Kendall Healthcare Products Company 510(k) Document Control Number: K933400

Description of the Device: The OLIGON™ FOLEY CATHETER is an all silicone, dual lumen Foley catheter (manufactured for Implemed, Inc. by Kendall Healthcare Products Company) which has been coated with Implemed's proprietary OLIGON™ material. The OLIGON™ coating is a patented silver based coating which has been shown in laboratory testing to actively release silver ions when exposed to saline. Under these test conditions, the 16 Fr catheters (91 cm^2 surface area) released a total of 3.4 milligrams of silver over 28 days and the 18 Fr catheters (96 cm^2 surface area) would release a total of 3.6 milligrams of silver over 28 days.

The OLIGON™ FOLEY CATHETER is supplied in two sizes; 16 Fr. and 18 Fr. (outer diameter). OLIGON™ Foley catheters are supplied sterile for single use. Individual catheters are packaged in sterilizable Tyvek/mylar pouches.

Intended Use of the Device: The subject device has the same intended use as the predicate device. The device is intended to pass fluids to or from the urinary tract.

Technological Characteristics: The technological characteristics of the OLIGON™ FOLEY CATHETER are substantially equivalent to those of the predicate device. Both the subject device and the predicate device conform to the requirements of the ASTM Standard F 623-89, entitled *Standard Performance Specification for Foley Catheter.* In addition, the OLIGON™ FOLEY CATHETER has been evaluated according to the applicable Parts of the

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ANSI/AAMI/ISO Standard 10993: *Biological Evaluation of Medical Devices* and has successfully met the biocompatibility requirements contained within the standard. Both the subject device and the predicate device are supplied sterile via EtO sterilization processes conforming to the ANSI/AAMI/ISO Standard 11135, entitled *Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.*

Functionally the OLIGON™ FOLEY CATHETER and the Kendall Curity 100% Silicone Foley Catheter are identical with respect to intended use of the catheter to pass fluids to and from the urinary tract. The only technological difference in the subject device and predicate device concerns the OLIGON™ coating of the OLIGON™ FOLEY CATHETER. The OLIGON™ coating applied to the surface of the subject device has been shown to release silver ions at a rate of $\geq 5.0 \times 10^{-5}$ mg/cm^2 · hour on first extraction. The predicate device does not have such a coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1999

Mr. Anthony Blank
Director, Regulatory and Clinical Affairs
Implemed, Inc.
313 Pleasant Street
Watertown, Massachusetts 02472

Re: K990509
Implemed Oligon™Foley Catheter
Dated: February 9, 1999
Received: February 18, 1999
Regulatory Class: II
21 CFR §876.5130/Product Code: 78 EZL

Dear Mr. Blank:

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

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: #K _____

Device Name: OLIGON™ FOLEY CATHETER

Indications for Use: The OLIGON™ FOLEY CATHETER is used to pass fluids to or from the urinary tract.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990509