

**Premarket Notification 510(k) Summary****AUG 18 2006****As required by section 807.92****Foley catheters with temperature probe (Foley Catheter with Temperature sensor, 14 F (M1024239), Foley Catheter with Temperature sensor, 16 F (M1024242), Foley Catheter with Temperature sensor, 18 F (M1024244))****GENERAL COMPANY INFORMATION as required by 807.92(a)(1)****COMPANY NAME/ADDRESS/PHONE/FAX:**

GE Healthcare  
86 Pilgrim Road  
Needham, MA 02492 USA  
Tel: 781-449-8685  
Fax: 781-433-1344

**NAME OF CONTACT:**

Mr. Joel Kent

**DATE:**

June 30, 2006

**DEVICE NAME as required by 807.92(a)(2)****TRADE NAME:****Foley catheters with temperature probe:**

Foley Catheter with Temperature sensor, 14 F (M1024239)  
Foley Catheter with Temperature sensor, 16 F (M1024242)  
Foley Catheter with Temperature sensor, 18 F (M1024244))

**COMMON NAME:**

Urinary catheter, with Temperature Probe

**CLASSIFICATION NAME:****The following Class II classifications appear applicable:**

FLL	Clinical electronic thermometer	21 CFR 880.2910
EYC	Catheter, Upper urinary Tract	21 CFR 876.5130
EZL	Catheter, Retention Type, Balloon	21 CFR 876.5130

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The disposable Foley catheters with temperature probe (REF M1024239, M1024242 and M1024244) are substantially equivalent in safety and effectiveness to the predicate DeRoyal disposable Foley catheters with temperature sensor (K041416).

DEVICE DESCRIPTION as required by 807.92(a)(4)

Disposable Foley catheters with temperature probe are used for drainage of the urinary bladder and simultaneous patient temperature measurement. These Foley catheters with temperature probe consist of the "Molex" plug connector on the adapter cable end, urine output flow path with a balloon and a thermistor inside the catheter. These probes are to be used with 400-series compatible temperature measurement systems only. The temperature probe measures temperature by a resistor that is sensitive to temperature changes. The probe is connected to the patient monitor by using an interconnect cable. These catheters have a skin and core contact with a patient. Catheters are shipped in sterile condition and there is a shelf life declared for each manufacturing batch. These Foley catheters with temperature probe can be used with legacy GE Medical System monitors like Dash 3000/4000 (K033304), Solar (K012467), TRAM (K900540) and also with the new GE Healthcare S/5 modules like M-PRESTN (K041772) and also with legacy Datex-Ohmeda patient monitors and modules like Cardiocap 5 (K992323), Light (K981378) or M-ESTPR (K953175). Products are packed inside a cardboard box having 25 pcs of individually packed products (inside a plastic/ paper pouch) in sterile condition. The package label describes product REF codes, manufacturing date, shelf life, CE-mark, legal entity information and a caution "Rx Only (USA), U.S. Federal law restricts this device to sale by or on the order of a physician." There is one instruction for use insert in the sales package of 25 probes.

INTENDED USE as required by 807.92(a)(5)

Intended use/Indication for use:

Foley catheters with temperature probe (REF M1024239, M1024242 and M1024244):

The Foley Catheter with Temperature Probe is intended for continuous temperature monitoring of patients who are catheterized because of fluid management problems, evaluation of urinary output, urine clearance following surgery or trauma involving pelvic organs, or obstruction or paralysis. Maximum indwelling: 29 days.

The temperature probes are designed for use with Datex-Ohmeda and GE Medical Systems IT monitoring systems and other monitors compatible with 400 Series temperature probes. Please consult your monitoring system manual for information specific to temperature probes usage. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The disposable Foley catheters with temperature probe (REF M1024239, M1024242 and M1024244) are substantially equivalent in safety and effectiveness to the predicate DeRoyal disposable Foley catheters with temperature sensor (K041416).

The disposable Foley catheters with temperature probe have the following identical features to the predicate device:

- Thermistor, materials, cable and cable surface, catheter and catheter material, plug interface and product dimensions

The proposed disposable Foley catheters with temperature sensor have the following differences compared to the predicate device:

- Labeling, artwork and a different wording of the instruction for use insert

In summary, disposable Foley catheters with temperature probe, described in this submission are substantially equivalent to the predicate DeRoyal Foley catheters with temperature sensor (K041416).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Foley catheters with temperature probe (REF M1024239, M1024242 and M1024244) have been assessed against the standards below. The devices have been thoroughly tested through validation and verification of specifications.

- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- IEC 60601-2-49:2001 (Part 2:-49: Particular requirements for the safety of multifunction patient monitoring equipment)
- 21 CFR Part 898
- ISO 15223:2000 Medical Devices - Symbols to be used with medical device labeling and information to be supplied
- EN 980+A1+A2 Graphical symbols for use in the labeling of medical devices
- ISO 10993-xBiological evaluation of medical devices
- ISO 14971:2000 Medical devices – Application of risk management to medical devices
- 510(k) Sterility Review Guidance K90-1;Guidance for Industry and FDA, August 30, 2002

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Foley catheters with temperature probe (REF M1024239, M1024242 and M1024244) as compared to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

AUG 18 2006

Mr. Joel C. Kent  
Manager, Quality and Regulatory Affairs  
GE Healthcare  
86 Pilgrim Road  
NEEDHAM MA 02492

Re: K061918

Trade/Device Name: Foley Catheter with Temperature sensor, 14 F (M1024239)  
Foley Catheter with Temperature sensor, 16 F (M1024242)  
Foley Catheter with Temperature sensor, 18 F (M1024244)

Regulation Number: 21 CFR §876.5130

Regulation Name: Urological catheter and accessories

Regulatory Class: II

Product Code: EYC

Dated: July 5, 2006

Received: July 6, 2006

Dear Mr. Kent:

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.



*Protecting and Promoting Public Health*

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  
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): K061918

Device Name: - Foley catheters with temperature probe (Foley Catheter with Temperature sensor, 14 F (M1024239), Foley Catheter with Temperature sensor, 16 F (M1024242), Foley Catheter with Temperature sensor, 18 F (M1024244))

### Indications for Use:

Foley catheters with temperature probe (REF M1024239, M1024242 and M1024244):

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

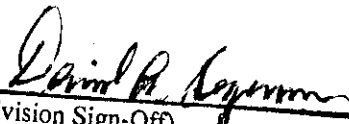
~~AND~~/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page    of   

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K061918