Premarket Notification 510(k) Summary
As required by section 807.92
Tympanic Temperature Probe with foam (M1024233) and
Tympanic Temperature Probe w/o foam (M1024237)

SEP 29 2006

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:

July 5, 2006

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Tympanic Temperature Probe with foam (M1024233)
Tympanic Temperature Probe w/o foam (M1024237)

COMMON NAME:

Temperature probe

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

FLL	Clinical electronic thermometer	21 CFR 880.2910

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

The disposable tympanic temperature probes (REF M1024233 and M1024237): are substantially equivalent in safety and effectiveness to the predicate DeRoyal temperature probes (K925792).

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

Disposable tympanic temperature probes are used during patient temperature measurement from the outer auditory canal. These probes consist of the "Molex" plug connector on the adapter cable end and a thermistor on the patient end. 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 probes have skin contact with a patient. Probes are shipped in non-sterile condition and there is a shelf life declared for each manufacturing batch. These temperature probes 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 probes (inside a plastic/paper pouch) in non-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 for tympanic probes (REF M1024233 and M1024237):

The Tympanic Temperature Probe is intended for atraumatic placement in proximity of the tympanic membrane.
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 the temperature probe usage.
The device is indicated for use by qualified medical personnel only

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

The disposable tympanic temperature probes (REF M1024233 and M1024237): are substantially equivalent in safety and effectiveness to the predicate DeRoyal temperature probes (K925792).
The disposable tympanic temperature probes have the following similarities to the predicate device:
- Have the same indicated use and shelf life
- Mechanical design, including colors, dimensions, materials and manufacturing processes are equal between GE Healthcare and DeRoyal tympanic probes
- Thermistor and functional performance are equal between GE Healthcare and DeRoyal tympanic probes
- Process of sterilization is equal between GE Healthcare and DeRoyal tympanic probes

The proposed disposable temperature probes have the following differences compared to the predicate device:
- Labeling, artwork, LOGO and different wording of the instruction for use insert

In summary, disposable temperature probes, described in this submission are substantially equivalent to the predicate DeRoyal tympanic temperature probes (K925792).

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

Tympanic Temperature Probe with foam (M1024233) and Tympanic Temperature Probe w/o foam (M1024237) 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
- ISO 10993-x
- ISO 14971:2000 Medical devices – Application of risk management to medical devices

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Tympanic Temperature Probe with foam (M1024233) and Tympanic Temperature Probe w/o foam (M1024237) as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP 2 9 2006

Re: K061942
Trade/Device Name: Tympanic Temperature Probe with Foam (M1024233) and Tympanic Temperature Probe w/o Foam (M1024237)
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 5, 2006
Received: July 10, 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 (PMA), 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 (240) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061942

Indications for Use

510(k) Number (if known): _____

Device Name: Tympanic Temperature Probe with foam (M1024233) and Tympanic Temperature Probe w/o foam (M1024237)

Indications for Use:

Intended use & Indication for use for tympanic probes (REF M1024233 and M1024237):

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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