SEP 2 0 2005

K051873

Premarket Notification 510(k) Summary
As required by section 807.92
Disposable Temperature Probes (M1024222, Skin Temperature Probe M1024231, GP Temperature Probe, Adult M1024229, GP Temperature Probe, Pediatric M1024205, Esophageal Stethoscope w/Probe, 9 Fr M1024212, Esophageal Stethoscope w/Probe, 12 Fr M1024215, Esophageal Stethoscope w/Probe, 18 Fr M1024218, Esophageal Stethoscope w/Probe, 24 Fr)

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 7, 2005

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

TRADE NAME:

Disposable Temperature Probes
M1024222, Skin Temperature Probe
M1024231, GP Temperature Probe, Adult
M1024229, GP Temperature Probe, Pediatric
M1024205, Esophageal Stethoscope w/Probe, 9 Fr
M1024212, Esophageal Stethoscope w/Probe, 12 Fr
M1024215, Esophageal Stethoscope w/Probe, 18 Fr
M1024218, Esophageal Stethoscope w/Probe, 24 Fr)

COMMON NAME:

Temperature probe

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

FLL	Clinical electronic thermometer	21 CFR 880.2910
BZT	Stethoscope, esophageal, with electrical conductors	21 CFR 868.1920

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

The disposable temperature probes (REF M1024231, M1024229, M1024222, M1024205, M1024212, M1024215 and M1024218) are substantially equivalent in safety and effectiveness to the predicate DeRoyal temperature probes (K925789, K925006, K925791).

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

Disposable temperature probes (Table below) are used during patient temperature measurement. 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. Esophageal stethoscopes with temperature probes have a dual role, in addition to temperature probe they can be used also as a stethoscope. 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 or core contact with a patient. Probes are shipped in sterile condition and there is a shelf life declared for each manufacturing batch.

REF	NAME
M1024222	Skin Temperature Probe
M1024231	GP Temperature Probe, Adult
M1024229	GP Temperature Probe, Pediatric
M1024205	Esophageal Stethoscope w/Probe, 9 Fr
M1024212	Esophageal Stethoscope w/Probe, 12 Fr
M1024215	Esophageal Stethoscope w/Probe, 18 Fr
M1024218	Esophageal Stethoscope w/Probe, 24 Fr

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 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.".

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

Intended use & Indication for use for GP probes (REF M1024231 and M1024229): The General Purpose Temperature Probe is intended for continuous temperature monitoring. The probe is inserted into the esophagus or the rectum. It is sterile and individually packaged. It has a low-friction surface finish to make the insertion easier. The temperature probe beneath the cuff at the distal tip is designed for use with Datex-Ohmeda and GE Medical Systems IT monitoring systems and other monitors compatible with 400 Series temperature probes.The device is indicated for use by qualified medical personnel only.

Intended use & Indication for use for skin probe (REF M1024222): The Skin Temperature Probe is intended for monitoring the skin surface temperature. It is sterile and individually packaged. There is a temperature sensor affixed to the center of the foam material on the adhesive cover. The disk-shaped adhesive cover has a reflective backing and a hypo-allergenic adhesive which follows closely the contour of the skin. The skin temperature probe is designed for use with Datex-Ohmeda and GE Medical Systems IT monitoring systems and other monitors compatible with 400 Series temperature probes. The device is indicated for use by qualified medical personnel only.

Intended use & Indication for use for esophageal probes (REF M1024205, M1024212, M1024215 and M1024218): The Esophageal Stethoscope with Temperature Probe is to be used for monitoring temperature, heart, and respiratory sounds on an anesthetized patient. The stethoscope tube is inserted into the esophagus. The probe is sterile, individually packaged and comes in different sizes. It has a low-friction surface finish to make the insertion easier, and a thin cuff to enhance sound transmission and fidelity. The stethoscope has a male luer fitting for attachment to a standard ear piece. The temperature probe, beneath the cuff at the distal tip, is designed for use with Datex-Ohmeda and GE Medical Systems IT monitoring systems and other monitors compatible with 400 Series temperature probes. 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 temperature probes (REF M1024231, M1024229, M1024222, M1024205, M1024212, M1024215 and M1024218) are substantially equivalent in safety and effectiveness to the predicate DeRoyal temperature probes (K925789, K925006, K925791).
The disposable temperature probes have the following similarities to the predicate device:
- Have the same indicated use and shelf life
- Mechanical design, including colours, dimensions, materials and manufacturing processes are equal
- Thermistor and functional performance are equal
- Process of sterilization is equal

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

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

The disposable temperature probes (REF M1024231, M1024229, M1024222, M1024205, M1024212, M1024215 and M1024218) have been assessed against the standards below. The device has 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)
- EN 12470-4, Performance of Electrical Thermometers
- 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 disposable temperature probes (REF M1024231, M1024229, M1024222, M1024205, M1024212, M1024215 and M1024218) as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2005

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

Re: K051873
Trade/Device Name: Disposable Temperature Probes (GP probes (REF M1024231 and M1024205, Skin probe (REF M1024222) and Esophageal probes (REF M1024205, M1024212, M1024215 and M1024218)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 7, 2005
Received: July 11, 2005

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.

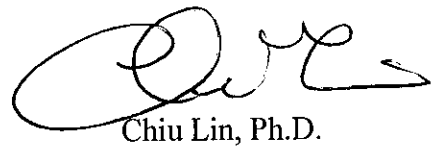
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications for Use

510(k) Number (if known): _____

Device Name: Disposable Temperature Probes (GP probes (REF M1024231 and M1024229), Skin probe (REF M1024222) and Esophageal probes (REF M1024205, M1024212, M1024215 and M1024218))

Indications for Use:

GP probes (REF M1024231 and M1024229): The General Purpose Temperature Probe is intended for continuous temperature monitoring. The probe is inserted into the esophagus or the rectum. It is sterile and individually packaged. It has a low-friction surface finish to make the insertion easier. The temperature probe beneath the cuff at the distal tip is designed for use with Datex-Ohmeda and GE Medical Systems IT monitoring systems and other monitors compatible with 400 Series temperature probes.The device is indicated for use by qualified medical personnel only.

Skin probe (REF M1024222): The Skin Temperature Probe is intended for monitoring the skin surface temperature. It is sterile and individually packaged. There is a temperature sensor affixed to the center of the foam material on the adhesive cover. The disk-shaped adhesive cover has a reflective backing and a hypo-allergenic adhesive which follows closely the contour of the skin. The skin temperature probe is designed for use with Datex-Ohmeda and GE Medical Systems IT monitoring systems and other monitors compatible with 400 Series temperature probes. The device is indicated for use by qualified medical personnel only.

Esophageal probes (REF M1024205, M1024212, M1024215 and M1024218): The Esophageal Stethoscope with Temperature Probe is to be used for monitoring temperature, heart, and respiratory sounds on an anesthetized patient. The stethoscope tube is inserted into the esophagus. The probe is sterile, individually packaged and comes in different sizes. It has a low-friction surface finish to make the insertion easier, and a thin cuff to enhance sound transmission and fidelity. The stethoscope has a male luer fitting for attachment to a standard ear piece. The temperature probe, beneath the cuff at the distal tip, is designed for use with Datex-Ohmeda and GE Medical Systems IT monitoring systems and other monitors compatible with 400 Series temperature probes. The device is indicated for use by qualified medical personnel only.

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)

Page __ of ___

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K951873