K060649



# 510(k) Summary

MAY 2 2 2006

**Date Summary Was Prepared:** March 9, 2006

**Submitter's Information:**

Kendall
a Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
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**Contact:**

Keith Martin
Manager, Regulatory Affairs
Kendall, a Division of Tyco Healthcare Group LP
Telephone: 508-261-8440
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**Device Trade Name:** Kendall Genius 2 Infrared Tympanic Electronic Thermometer

**Device Common Name:** Tympanic Thermometer

**Classification Panel:** General Hospital

**Legally Marketed Devices to Which Substantial Equivalence is Claimed:**
The Kendall Genius 2 Infrared Tympanic Electronic Thermometer is substantially equivalent to the Kendall FirstTemp Genius Tympanic Thermometer (K920713) in intended use, materials, physical characteristics, and performance characteristics. The primary modifications attributed to the predicate device are the addition of the axillary equivalent reading, an improved algorithm for determining offsets, and improved accuracy.

**Device Description:**
The Genius 2 is a new infrared tympanic electronic thermometer comprised of a battery operated handheld thermometer unit tethered to a base station. This Class II device is an electronic clinical thermometer that measures temperature by sensing infrared emmisions from the tympanic membrane in the ear canal. Through offest adjustments, equivalent site temperatures can be displayed for oral, rectal, core, and axillary temperatures based on the tympanic reading. This clinical electronic thermometer offers a streamlined graphical user interface that walks the user through temperature measurement.

The Genius 2 is designed to be compatible with the Tyco Healthcare/Kendall brand of disposable probe tip covers for patient safety and comfort. Probe covers are an existing legally marketed device and are not part of this 510(k) premarket notification submission. The Genius 2 is also designed to be compatible with the current FirstTemp Genius Field Calibrator for testing and verification of calibration status only.

**Intended Use:**
The Kendall Genius 2 Infrared Tympanic Electronic Thermometer is intended for use in patients in Acute and Alternate care settings to provide temperature measurements from the tympanic membrane and equivalent measurements of core, oral, rectal, and axillary temperature based on the tympanic reading. The indications and intended use are the same as the predicate device, with the exception of the added axillary temperature equivalent.

**Performance Data:**
Performance data for the Kendall Genius 2 Infrared Tympanic Electronic Thermometer is compared to that of the predicate device identified in this 510(K) summary. Results of verification / validation demonstrate that the modified device is substantially equivalent to the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2006

Mr. Keith Martin
Manager, Regulatory Affairs
Kendall, Tyco Healthcare Group, LP
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K060649
Trade/Device Name: Kendall Genius 2 Infrared Tympanic Electronic Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 9, 2006
Received: March 13, 2006

Dear Mr. Martin:

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.

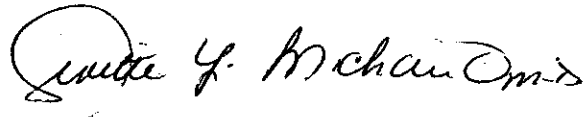
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K060649

Device Name: Kendall Genius 2 Infrared Tympanic Electronic Thermometer

Indications For Use:

The Kendall Genius 2 Infrared Tympanic Electronic Thermometer is intended for use in patients in Acute and Alternate care settings to provide temperature measurements from the tympanic membrane and equivalent measurements of oral, core, rectal, and axillary temperature based on the tympanic reading.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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