K072635

510(k) Summary

JAN 17 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is:_____

1. Applicant Device Information

Trade/Proprietary Name: Clinical Electronic Thermometers, Model MT901, Model MT518, Model ECT-1

Common Name: Clinical electronic thermometer.

Classification Name: Thermometer, electronic, clinical

Device Class: II

Product Code: FLL

Regulation Number: 880.2910

Intended Use:

The applicant device of Clinical Electronic Thermometers, Model MT901, Mode MT518, Mode ECT-1 are the electronic thermometers by using a thermistor as the temperature sensor to measure the body temperature in oral, axillaries (underarm use), and rectal.

2. Submitter Information

Establishment Registration Name:

Ningbo HuaHui Medical Instruments Co., LTD
No. 10 Jiangshantou Cun, Jiangshan Town,
Ningbo City, China 315191

Contact Person of the Submission:

Ms. Diana. Hong, Mr. Eric. Chen
Shanghai Mid-link Consulting Co., Ltd.
Suite 8D, Zhongxin Zhongshan Building,
No. 19, Lane 999, Zhongshan 2nd Road (S)
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Cellphone: +86 1391 6364 846
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Please CC: Eric.chen@mid-link.net

3. Predicate Device

Rapid Digital Thermometer, Model RDT-1 8-XY (X=0-9, Y=1-9)

K-number: K062016

Product Code: FLL

Intended Use:

The Rapid Digital Thermometer is an electronic thermometer used to measure body temperature in oral, axillaries (underarm use), and rectal.

Manufactured by:

Choice Smart Health Care Company Limited.
RM 1901, CC WU BUILDINQ
302 HENNESSY ROAD,
WANCHAI
Hong Kong

4. Device Description

The applicant device of Clinical Electronic Thermometers, Model MT901, Model MT518, Model ECT-1 are the electronic thermometers by using a thermistor as the temperature sensor. tor as the temperature sensor. The signal of sensor is calculated and displayed by an ASIC (Application Specific IC), JA31106, the CMOS digital clinical thermometer IC for measuring body temperature from 32.0°C ~ 42.0°C (90°F ~ 109.0°F)

All variants follow same design, same application with same performance and safety. The only difference is appearance. Therefore, all variants have same specifications parameters, same PCB Design, and same components with exception of shell.

No antimicrobial or antithrombotic ingredient is applied on the applicant device.

No chemical for the enhancement of its clinical performance is applied on or incorporated into applicant device.

No specific drug or biologic is applied with the applicant device.

5. Substantially Equivalence

Comparison Analysis:

The applicant device has same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The only differences are device weight and storage condition which are too slight to affect the device effectiveness and safety. No new design is applied. No new material is applied. No new question is raised.

Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2008

Ningbo HuaHui Medical Instruments Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Midlink Business Consulting Company, Limited
Suite 8D Zhongxin Zhongshan Building
No. 19, Lane 999, Zhongshan 2nd Road (S)
Shanghai, 200030
CHINA

Re: K072635
Trade/Device Name: Clinical Electronic Thermometers, Model MT901, Model MT518, Model ECT-1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometers
Regulatory Class: II
Product Code: FLL
Dated: January 2, 2008
Received: January 10, 2008

Dear Ms. Hong:

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) 276-0120. 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:_____

Device Name: Clinical Electronic Thermometers, Model MT901, Model MT518, Model ECT-1

Indications for Use:

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Prescription Use _____ (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)

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

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