DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Ji Bo
General Manager
Hangzhou Hua'an Medical & Health Instrument Company Limited
Building 2, Baimiao Industrial Park,
Economic Development Zone Wuchang
Hangzhou Zhejiang
P.R. CHINA 310023

JAN - 7 2010

Re: K092447
Trade/Device Name: Digital Thermometer, Digital Thermometer (Water-Proof), Digital Basal Thermometer, Digital Flexible Thermometer, Rapid Digital Thermometer, Rapid Digital Flexible Thermometer, Digital Pacifier Thermometer
Regulation Number: 21CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 15, 2009
Received: December 15, 2009

Dear Mr. Bo:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092447

Device Name:

Digital Thermometer	DT-01A, DT-01B, DT-01D, DT-01E, DT-01G,
Digital Thermometer (Water-proof)	DT-11A, DT-11B, DT-11D, DT-11E
Digital Basal Thermometer	DT-12
Digital Flexible Thermometer	DT-101A, DT-111A, DT-101B, DT-111B
Rapid Digital Thermometer	DT-K01A, DT-K11A
Rapid Digital Flexible Thermometer	DT-K101A, DT-K111A
Digital Pacifier Thermometer	DT-201A, DT-211A

Indication For Use:

The devices models DT Series (barring model DT-201A and DT-211A) are electronic clinical thermometer intended to measure the human body temperature in regular mode orally, rectally or under the arm, the devices are reusable for clinical or home use on people of all ages.

The device model DT-201A and DT-211A are electronic clinical thermometer with pacifier probe head intended to measure oral temperature. The device is reusable for clinical or home use for children under the age of four.

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 IF 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: K092447