



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

November 7, 2012

Mr. Ahneo Yang  
Regulatory Affairs & Quality Assurance Manager  
Hangzhou Hua'an Medical & Health Instruments Company, Limited  
Building 2, Baimiao Industrial Park, Economic Development Zone  
Wuchang Hangzhou, Zhejiang 310023 P.R. China

Re: K122912

Trade/Device Name: Rapid Digital Thermometer DT-K11B, Rapid Digital Flexible  
Thermometer DT-K111B DT-K11D, Digital Flexible  
Thermometer DT-111G DT-111D, Digital Thermometer  
(Water-proof) DT-11G, Predictive Digital Thermometer  
DT-Y111D

Regulation Number: 21 CFR 880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

Dated: October 16, 2012

Received: October 19, 2012

Dear Mr. Yang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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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,

Digitally signed by Anthony D. Watson  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,  
cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402  
Date: 2012.11.07 12:19:09 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.

Director

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

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Attachment 2**

K122912/5001

**Indications for Use Statement**

510(k) Number (if known):

**Device Name:**

Rapid digital thermometer	DT-K11B
Rapid digital flexible thermometer	DT-K111B DT-K111D
Digital flexible thermometer	DT-111G DT-111D
Digital thermometer(Water-proof)	DT-11G
Predictive digital thermometer	DT-Y111D

**Indications for Use**

The devices models DT-K11B, DT-K111B, DT-K111D, DT-111D, DT-111G, DT-11G, DT-Y111D 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.

Prescription Use \_\_\_\_\_ AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X  
(Part 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)

 Actm for  
Richard Chapman

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

510(k) Number: K122912