DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shenzhen Everbest Machinery Industry Company, Limited
C/O Ms. Tamas Borsai
Responsible Third Party Official
TÜV Rheinland of North America, Incorporated
12 Commerce Road
Newton, Connecticut 06470

JUL - 6 2010

Re: K101736
Trade/Device Name: Infrared Thermometer Model DT-8806H/DT-8806/DT-886
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 17, 2010
Received: June 21, 2010

Dear Ms. Borsai:

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.

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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 04

PREMARKET NOTIFICATION

Indications for Use

510(k) Number (if known): K101736

Device Name: Infrared Thermometer
Trade Model Name: Infrared Thermometer
Model: DT-8806H/DT-8806/DT-886

Intended Use: Infrared Thermometer Model: DT-8806H/DT-8806 Non-contact body infrared thermometer is designed for body surface and forehead temperature measurement for infants and adults without contact to human body. The Digital Infrared Ear Thermometer Model: DT-886 can provide a stable, hear –interference –free reading with each measurement, The digital Infrared Thermometer is intended for the periodic measurement and monitoring of human body temperature, It is intended for use on people of all ages. The Infrared Thermometer can be used by consumers in household environment. It is manufactured in accordance with the ASTM E1965-1998 Standard specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

Infrared Thermometer Model: DT-8806H/DT-8806/DT-886 is medical instruments, used as an assistant device by normal people to evaluate, by the result of measurement, their decision for the next clinical step in order to protect human's health. The function for measuring human body's temperature with precision helps detect and observe human states of health, in case of any possible illness.

Infrared Thermometer Model: DT-8806H/DT-8806 is a hand-held, non-sterile, reusable medical device, Use and alcohol swab or cotton tissue moistened with alcohol(70% Isopropyl) to clean, the Digital Infrared Ear thermometer(DT-886) casing and the measuring probe contact body. supplied by internal power. It is used for human beings, and it belongs personal use monitoring device.

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Infrared Thermometer Model: DT-8806H/DT-8806 is non-contact device. It can detect the temperature from human's forehead, DT-886 is Digital Infrared Ear thermometer ,It can detect the temperature from human's ear channel ,It takes only half second(DT-8806/DT-8806H) and one second(DT-886) for one times measurement.

Valid scientific evidence of product testing reports, software verification, and substantial equivalence are provided to guarantee product function, safety, effectiveness, and biological compatibility, etc.

The thermometer shall be cleaned before and after each use. Cleaning method and information are provided in the instructions for use. (See Chapter 13)

Do not bite, bend, drop or disassemble this thermometer and do not dispose this thermometer and battery into fire. Keep this thermometer away from direct sunlight, moisture, dirt, extreme temperature while use, store or transport.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

RLC 7/8/10 ACTING BC CHIEF

(Division Sign-Off)
·vision of Anesthesiology, General Hospital
·ction Control, Dental Devices

·)0(k) Number: K101736