JUL 11 2002

IDT Technology Limited
萬威科研有限公司

510(k) Summary
FT101 Forehead Thermometer
FT101 Infrared Digital Thermometer
510(k) Number K020433

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1. APPLICANT'S INFORMATION:
   Stephen Li
   Vice President – Health Care Products
   IDT Technology Limited
   Block C, 9/F., Kaiser Estate, Phase 1
   41 Man Yue Street, Hunghom Hong Kong, CHINA
   Tel: (852) 2764 7873
   Fax: (852) 2765 6620
   Email: idthk@idthk.com
   Web Site: http://www.idthk.com
   Medical Establishment Registration No.: 9680516

2. SUBMITTER'S INFORMATION:
   James Jochen Rogers
   General Manager
   Coastal Consulting Group, Ltd.
   P.O. Box 391117
   Solon, OH 44139
   PH/FX: 440.546.4936
   Mobile: 412-596.2578
   E-mail: coastalcg@earthlink.net

3. Date: February 6, 2002

4. DEVICE INFORMATION
   DEVICE NAME: Clinical Electronic Thermometer
   Classification Panel: General Hospital
   Classification Number: 882.2910 Clinical Electronic Thermometer
   Product Nomenclature: Thermometer, Clinical, Electronic
   Product Code(s): 80FLL
   Trade/Proprietary Name: FT101 Forehead Thermometer; FT101 Infrared Digital Thermometer
   Common Name: Electronic Thermometer

5. DEVICE CLASSIFICATION:
   Clinical Electronic Thermometers are Class II devices, and are reviewed by the General Hospital Division.

TÜV PRODUCT SERVICE Quality sy certified t ISO 9002

6. PREDICATE DEVICE(S):
   ThermoTek IR Forehead Thermometer Model 718F, K002712, currently in commercial distribution in the US.

7. DEVICE DESCRIPTION:
   The FT101 Forehead Thermometer is an over-the-counter, non-sterile, reusable, non-predictive clinical electronic thermometer designed to measure and assess the temperature of humans of all age ranges using an infrared detector to detect heat emission from the forehead. The measured temperature correlates to axillary temperature, and is displayed on a built-in LCD display. Calendar/clock functions are provided, and a memory function stores up to 10 temperature readings.

   The temperature reading range is 34°C – 42.2°C (92.3°F to 108.0°F), and the time of measurement is approximately 2 seconds, with a recommended cycle time of at least 30 seconds between readings. The unit operates in an ambient temperature range of 16°C – 35°C (61°F to 95°F). The FT101 Forehead Thermometer is entirely self-contained within one housing, and is battery-powered. The device is compact in size and weight, easy to use, portable and may be used in a variety of home or clinical settings.

8. INDICATIONS FOR USE:
   The FT101 Forehead Thermometer is an over-the-counter, non-sterile, reusable, infrared clinical electronic thermometer intended for the intermittent measurement of the outer surface temperature of the human body of people of all ages.

9. TECHNOLOGICAL CHARACTERISTICS:
   The manufacturer believes that the technological characteristics of the FT101 is substantially similar to those of the predicate device.

10. PERFORMANCE DATA:
    The FT101 conforms with the following voluntary standards: EN 60601-1/A13, EN 60601-1-2. Additionally, safety and efficacy performance of the device has been established clinically and non-clinically through comparative testing to market-cleared devices in accordance with ASTM E1965-98 and prEN 12470-5 voluntary standards, and without raising new safety or effectiveness issues.

11. STATEMENT OF SUBSTANTIAL EQUIVALENCE:
    Based upon the safety and performance testing and compliance with voluntary standards, the manufacturer believes that the FT101 Forehead Thermometer is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

IDT Technology Limited
C/O Mr. James J. Rogers
General Manager
Coastal Consulting Group, Limited
P.O. Box 391117
Solon, Ohio 44139

Re: K020433
Trade/Device Name: FT 101 Forehead Thermometer, FT 101 Infrared Digital Thermometer
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 11, 2002
Received: May 14, 2002

Dear Mr. Rogers:

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.

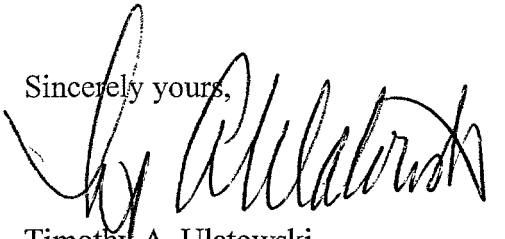
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020433

Device Name: FT101 Forehead Thermometer
FT101 Infrared Digital Thermometer

Indications for Use:

The FT101 Forehead Thermometer is an over-the-counter, non-sterile, reusable, infrared clinical electronic thermometer intended for the intermittent measurement and assessment of the skin forehead temperature of humans of all age ranges. The measured temperature correlates to axillary temperature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801-109

Patricia Cucanta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020433

(Optional Format 1-2-96)