APR - 9 2002

K021652

# GLOBAL TREASURE INDUSTRIES LIMITED

Block 2, 5/F, Room 8, Nan Fung Ind. City, No. 18, Tin Hau Road,
Tuen Mun, New Territories, Hong Kong
Tel: (852)24541493; Fax: 24546187; E-mail: glotr@netvigator.com

## The Non-confidential summary of safety and Effectiveness

The summary of 510k safety and effective new information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR807.92. The assigned 510k number is K_____(to be assigned)

Dated of summary prepared: March 12, 2002

| | | |
|---|---|---|
| 1. | Submitter's identification<br>Global Treasure Industries Limited<br>Block 2,5F. , Room 8 , Nan Fung Ind. City, 18 Tin Hau Road, Tuen Mun, N.T., Hong Kong<br>Tel:(852)24541883 FAX:(852)24546187 | |
| 2. | Official contact: | Ben Ma – General Manager |
| 3. | Trade name: | GT010706 sec Digital thermometer |
| 4. | Common name: | Clinical electronic thermometer |
| 5. | Classification name: | 80FLL, Clinical electronic thermometer subsection 880.2910 |
| 6. | Intended device: | Clinical electronic thermometer |
| 7. | Predicate devices: | Wiltec Industries Ltd-Electronic Thermometer-K961879 |
| 8. | Device description: | The intended product is an electronic digital thermometer for measuring patient temperature. |
| 9. | Intended use: | |
| 9.1 | Indicated use-to measure patient temperatures-orally, axillary and rectal. | |
| 9.2 | Targeted population-Any patient requiring body temperatures measured | |
| 9.3 | Environment of use-Hospital and home | |
| 10. | Comparison to predicate devices: | |
| 10.1 | Side by side Comparison Table | |

| | Element of comparison | Subject device Global Treasure Industries GT010706 | Claimed SE device Wiltec:K961879 |
|---|---|---|---|
| a. | Use | | |
| | Indicated for taking temperature | Yes | Yes |

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| 10.1 | Side by side Comparison Table (continued) | | |
|---|---|---|---|
| b. | Types of temperature | | |
| | Oral | Yes | Yes |
| | Underarm | Yes | Yes |
| | Rectal | Yes | Yes |
| | Digital/electronic thermometer | Yes | Yes |
| c. | Design | | |
| | LCD display | Yes | Yes |
| | Temperature increments of 0.1° F | Yes | Yes |
| | Sensor type- thermistor | Yes | Yes |
| | Signal processing-CMOS | Yes | Yes |
| | Power –Button battery 1.5V | Yes | Yes |
| | On / off button | Yes | Yes |
| | Buzzer | Yes | Yes |
| | Removable battery case | Yes | Yes |
| | Cleaned with alcohol | Yes | Yes |
| d. | Material | | |
| | Case | ABS and Thermoplastic Elastomer | ABS |
| | Sensor cover | Stainless steel | aluminium |
| e. | Performance testing | | |
| | Temperature range | 90.0-109.9° F | 89.6-109.4° F |
| | Ambient temperature | 60.8-104° F | 60.8-104° F |
| | Beeps alarum | Yes | Yes |
| | Response time | About 20 seconds | About 1 minute |
| | Automatic shut off | Yes | Yes |
| f. | Accuracy and Performance meets | | |
| | ASTM E1112 | Yes | Yes |
| 10.2 | Difference | | |

| | |
|---|---|
| (a) | There are several difference in between the subject and legally marketed devices :<br>- the subject device has a quicker response time<br>- the subject device compose of different material : thermoplastic elastomers and stainless steel probe<br>- the subject device has a slight difference in the working range of measurement |
| (b) | Although there are differences in between the subject device and the legally marketed one, they do not affect the safety, performance and accuracy of the subjected device. All the materials used are non-toxic and in compliance with EN ISO 10993. The performance and accuracy are in compliance with ASTM requirements.<br>The subject device is still considered to be substantially equivalent to the legally marketed one. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2002

Global Treasure Industries Limited
C/O Mr. Ned Devine, Jr
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K021052
Trade/Device Name: Model GT010706 Electronic Thermometer
Regulation Number: 880.2910
Regulation Name: Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 12, 2002
Received: April 1, 2002

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of April 9, 2002 regarding the company name.

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). 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.

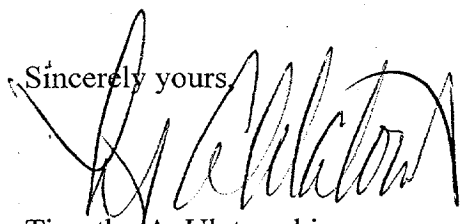
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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 Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## D. Indications for Use Statement

Pursuant to the Notice regarding listing of indications for Use on a separate sheet, the following is per that request.

510(k) Number_____(To be assigned)

| | |
|---|---|
| Device name: | Clinical electronic thermometer |
| Indications for use: | |
| Indicated use- | Measure of individual temperature |
| Measurements- | Oral |
| | Axillary -under arm |
| | Rectal |
| Range of measurement- | 90.0° - 109.9° F (32.0° - 43° C) |
| Accuracy- | +/-0.2° F |
| Targeted population- | Individuals requiring temperature measurements |
| Environment of use- | Hospital and home |
| Disposable / reusable- | Reusable, clean with alcohol |

Concurrence of CDRH, Office of Device Evaluation(ODE)

PRESCRIPTION USE_____ OR OVER-THE-COUNTER USE___✓___

(PER 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021052