ORIENTAL SYSTEM TECHNOLOGY INC.

K042202

1 of 3

SEP 1 0 2004

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and CFR§807.92.

The assigned 510(k) number is:_____

1. Submitter's Identifications:

Oriental System Technology Inc.
2F No.23, Industry E, Road 9th,
Science Based Industrial Park
Hsinchu, Taiwan, R.O.C

Contact:

Mr. Herman Lee
General Manager

Date of Summary Preparation: August 12, 2004

2. Name of the Device:

TempTeller-High Speed Digital Thermometer , Model DT302 ,DT312 , DT412,DT502

3. Information of the 510(k) Cleared Device (Predicate Device):

1. TempTeller- Digital Thermometers, Model DT-102
   510(k) Number: K#992601
2. VICKS – Speed Read Digital Thermometer , Model V911 , V965

4. Device description:

The OSTI Temp-Teller High Speed Digital Thermometer(Model DT-302 , DT-312 , DT-412 , DT-502) is an electronic thermometer using a thermistor as the temperature sensor . The sensor's electric signal is calculated and displayed by an ASIC (Application Specific IC)

The High Speed digital thermometer comprises: a thermistor for temperature sensing , a reference resistor for comparing the resistance of the thermistor , a buzzer for sounding effect , an ASIC and a LCD display for calculating and displaying the target temperature digitally . The system uses a 1.55 V battery

for the power supply and the battery power is automatically check by the ASIC and displayed in LCD if the battery is exhausted .

The OSTI Temp-Teller High Speed Digital Thermometer (Model DT-302 , DT-312 , DT-412 , DT-502) can makes temperature taking faster , its temperature stabilize reading within 10 sec in a 37℃ water bath at ambient temperature 23+/-2℃ .

DT-312 ,DT-412 is high speed digital thermometers, with flexible front tip and with power /measuring button set aside with LCD display and with water resistant function .

DT502 is high speed digital thermometers, with rigid front tip and with power /measuring button set aside with LCD display and with water resistant function .

DT302 is high speed digital thermometers, with rigid front tip and with power /measuring button on top end and with water resistant function .

The DT-302 , DT-312 ,DT-412 , DT-502 is identical in functionality and performance .

The essential change include 1)Metal cap / Thermistor mechanical structure change to improve thermal transmission 2)Firm ware 3)Material 4)Shape layout and dimension .

The fundamental scientific technology of the modified device remains the same as that of the 510(k) cleared device.

5. Intended Use:

The device is an electronic clinical thermometer using a thermistor to detect body temperature from the oral , armpit , and rectal in neonatal , pediatric and adult population used in the clinical and home testing .

6. Comparison to Predicate Devices:

The OSTI Temp Teller High Speed Digital Thermometer , Model DT-301,DT-312 , DT-412 ,DT-502are substantially equivalent to the following digital thermometers.

1.TempTeller- Digital Thermometers, Model DT-102
510(k) Number: K#992601

2.VICKS – Speed Read Digital Thermometer , Model V911 , V965

The OSTI Temp Teller High Speed Digital Thermometer , Model DT-301,DT-312 ,DT-412 ,DT-502 have the same intended use as and are similar in design to the 510(k) cleared device.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards include ASTM E 1112-2000 , as well as IEC 601-1-1 and IEC 601-1-2 requirements.

FDA Guidance documents include the" Deciding When to Submit a 510(k) for a Change to An Existing Device" and "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

8.Discussion of Clinical Tests Performed :

Controlled human clinical studies were conducted using the OSTI Temp Teller Thermometer and predicate devices . Clinical data is presented with readings representing a conventional /currently accepted reading by oral or rectal temperature .

9. Conclusions

The OSTI TempTeller –High Speed Digital thermometers, model DT302 , DT312 , DT412,DT502 have the same intended use and technological characteristics as the 510(k) cleared device. Moreover, verification and validation tests contained in this submission demonstrate that the modified portions maintained its original safety and effectiveness. Those engineering changes do not: (1) affect the intended use or (2) alter the fundamental scientific of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2004

Oriental System Technology, Incorporated
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K042202
Trade/Device Name: Temp Teller-High Speed Digital Thermometers, Models DT-302, DT-312, DT-412, DT-502
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 3, 2004
Received: September 7, 2004

Dear Ms. Goldstein-Falk:

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042202

Exhibit B

510(k) Number (if known): _____

Device Name: Oriental System Technology Inc. Temp Teller High Speed Digital Thermometers, Models DT-32, DT-312, DT-412, DT502.

Indications For Use:

The device is an electronic clinical thermometer using a thermistor to detect body temperature from the oral, armpit and rectal in the neonatal, pediatric and adult population used in clinical and home testing.

Prescription Use _____ (Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use X (21 CFT 807 Subpart C)

Irene Raveane for ADW 9/10/04

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

510(k) Number: K042202

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_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)