

OCT 27 1999

K 992601

EXHIBIT # 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: \_\_\_\_\_.

1. Submitter's Identification:

Oriental System Technology Inc.  
2F No. 23, Industry E. Road 9<sup>th</sup>  
Science Based Industrial Park  
Hsinehu, Taiwan, R.O.C.

Contact:

Mr. Herman Lee  
General Manager

Date Summary Prepared: July 1999

2. Name of the Device:

Temp Teller-Digital Thermometer, Models DT-101, DT-102, DT-103, DT-201, DT-202, and DT-203.

3. Predicate Device Information:

1. Q-Tips®, Faichney, Private Label Clinical Electronic Thermometers  
K# 962497
2. Wallgreens PAP-WD

4. Device Description:

The OSTI Temp – Teller Digital Thermometer, (Models DT-101, DT-102, DT-103, DT-201, DT-202, and DT-203), is an electronic thermometer using a thermistor as the temperature sensor. The sensor's electric signal is then calculated and displayed by an ASIC (Application Specific IC) Models DT-101 and DT-201 display the temperature within a 100<sup>th</sup> of a degree. Models DT-101, DT-102 and DT-103 employ a 1.5 times larger LCD display than competitive products for easier reading. Models DT-101, DT-102, DT-201 and DT-202 have a water-resistant function.

The 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 which the thermistor is immersed.

The system uses a 1.5V DC battery for the power supply and the battery power is automatically checked by the microprocessor and displayed in LCD if the battery is exhausted.

5. **Intended 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 the clinical and home testing.

6. **Comparison to Predicate Devices:**

The OSTI Temp Teller – Digital Thermometer, Models DT-101, DT-102, DT-103, DT-201, DT-202, and DT-203 are substantially equivalent to the following digital thermometers.

- a. Q-Ips®, Faichney, Private Label Clinical Electronic Thermometers K# 962497
- b. Wallgreens PAP-WD

The OSTI Temp Teller Digital Thermometer is similar in design and intended use to the predicates differing only in ambient range and resolution. All products use the same temperature sensing element – thermistor as well as the use of a metal cap to protect the thermistor, an LCD display, ASIC, a buzzer and a 1.55V battery.

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

Compliance to applicable voluntary standards includes ASTM E1112, and ASTM E1104, as well as IEC 60601-1 and IEC 60601-1-2 requirements.

Guidance Documents included the FDA “Guidance On The Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers”.

8. **Discussion of Clinical Tests Performed:**

Controlled human clinical studies were not conducted using the OSTI Temp Teller Digital Thermometer and predicate devices.

9. **Conclusions:**

The OSTI Temp Teller – Digital Thermometer, Models DT-101, DT-102, DT-103, DT-201, DT-202, and DT-203, have the same intended use and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the OSTI Temp Teller Digital Thermometer, Models DT-101, DT-102, DT-103, DT-201, DT-202, and DT-203 is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 27 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Oriental System Technology, Incorporated  
C/O Ms. Susan D. Goldstein-Falk  
Official correspondent for  
Oriental System Technology, Incorporated  
MDI Consultants, Incorporated  
55 Northern Boulevard, Suite 410  
Great Neck, New York 11021

Re: K992601

Trade Name: Temp Teller - Digital Thermometer, Models  
DT-101, DT-102, DT-103, DT-201, DT-202, and DT-203  
Regulatory Class: II  
Product Code: FLL  
Dated: July 30, 1999  
Received: August 3, 1999

Dear Ms. Susan D. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

510(k) Number (if known): \_\_\_\_\_

Device Name: Oriental System Technology Inc. Temp Teller Digital  
Thermometer, Models DT-101, DT-102, DT-103,  
DT-201, DT-202, DT-203

**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 the clinical and home testing.

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PAGE IF NEEDED)

\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use   
(Optional Format 1-2-96)

Patricia Curran

(Division sign-off)  
Division of Dental, Infection control,  
And General Hospital Devices

510(k) number K892601