MAY 2 6 1999

K984497

EXHIBIT # 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

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

Contact:

Mr. Herman Lee
General Manager

Date Summary Prepared: November 1998

2. Name of the Device:

Temp Teller-Infrared Tympanic Thermometer, Models TT-200 and TT-201

3. Predicate Device Information:

ThermoScan Instant Thermometer, K# 902912, K# 930680, K# 954523 and K# 964605, ThermoScan Inc.

Omron Gentle Temp MC 505, K# 922344, Omron Health Care.

4. Device Description:

The OSTI Temp – Teller Infrared Tympanic Thermometer, Models TT-200, TT-201, is an electronic thermometer using an infrared sensor (pyroelectric heat sensor, employing the principle of the electrically calibrated pyroelectric radiometer (ECPR)) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces.

OSTI Temp –Teller Infrared Tympanic Thermometer, Model TT-200, TT-201, consists mainly of five parts: an IR sensor, a barrel, a shutter, an ambient temperature sensor, and the associated circuit.

The ear canal guides sound to the eardrum, which is thin and flooded with blood at the core temperature. The barrel, usually a cylindrical pipe with a highly reflective inner surface for confining the radiation, is adaptive to the outer canal without contracting the eardrum. The shutter controls when the flux is transferred to the IR sensor. When the shutter is open, radiative fluxes transfer among the tympanum, the IR sensor, and the inner surface of the barrel. The ambient sensor is mounted near the IR sensor to monitor the ambient temperature.

To measure core temperature, a tympanic thermometer is inserted into a patient's outer ear canal. A start button is pressed to open the shutter momentarily and to start the measurement through the radiation exchanges. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The measured temperature then appears on a display. The total operation takes a few seconds.

5. Intended Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. Comparison to Predicate Devices:

The OSTI Temp Teller – Infrared Tympanic Thermometer, Models TT-200 and TT-201 are substantially equivalent to the following infrared ear thermometers.

- ThermoScan Instant Thermometer, K# 902912, K# 930680, K# 954523 and K# 964605, ThermoScan Inc. and,
- Omron Gentle Temp MC 505, K# 922344, Omron Health Care.

The OSTI Temp Teller is similar in design and intended use to the predicates differing only in the infrared sensor used with auto calibration and/or method used to determine/control the reference temperature.

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 conducted using the OSTI Temp Teller Thermometer and predicate devices. Clinical data is presented comparing the IR thermometers to standard oral/rectal thermometers with readings representing a conventional/currently accepted reading, i.e., rectal or oral. The patient population is well represented (neonatal, pediatrics and adults), and the number of patients have been statistically justified.

9. Conclusions:

The OSTI Temp Teller – Infrared Tympanic Thermometer, Models TT-200 and TT-201, have the same intended use and similar technological characteristics as the ThermoScan Instant Thermometer and Omron Gentle Temp MC 505 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 Infrared Tympanic Thermometer, Models TT-200 and TT-201 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 1999

Oriental System Technology, Incorporated
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent for
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K984497
Trade Name: Temp Teller® Infrared Instant Ear Thermometer Model TT-201
Regulatory Class: II
Product Code: FLL
Dated: April 1, 1999
Received: April 5, 1999

Dear Ms. 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 (Premarket 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 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,

Susan Runner

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

Enclosure

Exhibit B

510(k) Number (if known): _____

Device Name: Oriental Systems Technology Inc. Temp – Teller – Infrared Tympanic Thermometer, Models TT-200, TT-201

Indications For Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

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

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K984497