AUG 0 6 2002

K021753

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:

E-Care Technology Corporation
8F-11, No.35, Hsin-Tai Road
Chubei City, Hsinchu,
Taiwan 302

Date Summary Prepared:

Contact: Kun-Yuan Ko

2. Name of the Device:

E-Care Infrared Ear Thermometer, Model LCT-200

3. Predicate Device Information:

Braun/ThermoScan Instant Thermometer, IRT3020, IRT3520, Braun Ltd. K#983295, ThermoScan Inc.

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

4. Device Description:

The E-Care Technology Corporation Infrared Ear Thermometer, Model LCT-200 is an electronic thermometer using an infrared detector (thermopile detector) 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 of the patient.

The E-Care Technology Corporation Infrared Ear Thermometer, Model LCT-200 consists mainly of four parts - an IR detector with a built in ambient temperature sensor, a barrel, an LCD display, 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 contacting the eardrum. When measuring, the radiative fluxes transfer from the tympanum through or reflected by the inner surfaces of the barrel to the IR detector. The ambient sensor is built-in and mounted near the IR sensor element to monitor the ambient temperature.

To measure core temperature, the ear thermometer is inserted into a patient's outer ear canal. A start button is pressed to start the measurement through 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 E-Care Infrared Ear Thermometer, Model LCT-200 is substantially equivalent to the following infrared ear thermometers.

Braun ThermoScan Instant Thermometer, IRT 3020, IRT3520, Braun Ltd., and,

Omron Gentle Temp MC-505, Omron Health Care.

The E-Care Infrared Ear Thermometer, Model LCT-200 uses the well know infrared radiation theory as the predicates and has the similar intended use to the predicates differing only in the infrared sensor used and/or method used to determine the reference ambient temperature.

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

Compliance to applicable voluntary standards includes ASTM E1965 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 E-Care Infrared Ear Thermometer, Model LCT-200 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 E-Care Infrared Ear Thermometer, Model LCT-200 has the same intended use and similar characteristics as the Braun/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 E-Care Infrared Ear Thermometer, Model LCT-200 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

AUG 0 6 2002

E-Care Technology Corporation
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard
Great Neck, New York 11021

Re: K021753
Trade/Device Name: E-Care Infared Ear Thermometer, Model LCT-200
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 24, 2002
Received: May 29, 2002

Dear Ms. 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 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

Exhibit B

510(k) Number (if known): K021753

Device Name: E-Care Infrared Ear Thermometer, Model LCT-200.

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 Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K021753