K112189

510(K) SUMMARY

JAN 13 2012

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

Date of Preparation: Sept. 1, 2011

1. Submitter's Name: **Digio2 International Co., LTD.**

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Contact: Casper Chen, President

2. Device Name

Trade Name: **Thermo Pal Infrared Ear Thermometer, Model no.: ETH-101**

Common Name: IR Thermometer

Classification name thermometer, electronic, clinical

3. Device Class: The **Thermo Pal Infrared Ear Thermometer, (Model no.: ETH-101)** has been classified as

Regulatory Class: II

Panel: 80

Product Code: FLL

Regulation Number: 21CFR 880.2910

4. Predicate Device: The predicate device is the

- **BRAUN THERMOSCAN IRT 4000 SERIES CLINICAL INFRARED EAR THERMOMETERS (K103800)** marketed by **BRAUN AG.**

5. Intended Use: The **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** is infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

6. Device Description:

The **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** is hand-held, non-sterile, reusable, battery operated device that can measure human body temperature via the human ear.

Operation is based on the measuring of the natural thermal infrared radiation emitted from the ear tympanic.

7. Comparison to 510(k) Predicate Devices & Substantial Equivalence Discussion

The **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** has the same intended use, principles of operation, and similar technological characteristics as predicate devices. Please find Technological Characteristics as follows

Item	**Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)**	**Predicate Device** Braun THERMOSCAN IRT4520/4020 Clinical Infrared Ear Thermometer (K103800)
Regulation Number:	21CFR 80.2910	21CFR 880.2910
Displayed Temperature Range	32~43°C (89.6~109.5°F)	34°°C~42.2°C (93.2°F~108°F)
Ambient Temperature Environment	1. Operating: 10°C~40 °C 2. Storage: -20°C~50°C	1. Operating: 10°C~40 °C 2. Storage: -20°C~50°C
Accuracy	±0.2°C, 36~39°C ±0.3°C, the rest (±0.4°F, 96.8~102.2°F ±0.5°F, the rest)	1. 36.0°C(96.8 °F) to 39.0°C(102.2°F): ± 0.2°C (0.4°F) 2. Outside this range: ± 0.3°C (0.5°F)
Resolution	0.1°C / 0.1°F	0.1°C / 0.1°F
Display	Three different backing color 4 digit LCD screen	Three different backing color 4 digit LCD screen
Components	Main components: 1. Chip IC (μP) 2. IR Sensor 3. LCD(Liquid Crystal Display)	Main components: 1. Chip IC (μP) 2. IR Sensor 3. LCD(Liquid Crystal Display)
Power requirements	Two 1.5Vdc Alkaline Manganese battery (AAA)	Two 1.5Vdc Alkaline Manganese battery (AAA)

SUBSTANTIAL EQUIVALENCE DISCUSSION:

Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101) has the same general design with the predicate devices. It has the following similarities to the predicate devices in:

- having the same intended use
- using similar operating principle
- using similar technological characteristics

In summary, the **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** described in this submission are, in our opinion, substantially equivalent to the predicate devices.

8. Non-Clinical Tests Verification

Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** are as the followings:

1) Performance Compliance Test according to **ASTM E1965: 2003** conducted by manufacturer
2) Electrical Safety Compliance Test according to **IEC 60601-1** by accredited laboratory.
3) **EMC** Compliance Test according to **IEC 60601-1-2** by accredited laboratory.

9. Clinical Test for Measurement Accuracy

Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:

A Clinical Test Report conducted according to **ASTM E1965: 2003** performed by the manufacturer was included as Clinical Investigation report. This report was carried out in such a way that compared the accuracy performance between **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** and the predicate device according to the method recommended in **ASTM E1965** standard.

The results of the Clinical Test Report could positively support the claim of Substantial Equivalence for **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** against the chosen 510K predicate device.

10. Conclusions:

The **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** has the same intended use and similar technological characteristics as the BRAUN THERMOSCAN IRT4520/4020 CLINICAL INFRARED EAR THERMOMETERS (K103800) marketed by BRAUN AG.. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics DO NOT RAISE ANY NEW QUESTIONS OF SAFETY OR EFFECTIVENESS. Thus, the **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 13 2012

Digio2 International Company, Limited
C/O Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corporation, USA
2904 N. Boldt Drive
Flagstaff, Arizona 86001

Re: K112189
Trade/Device Name: Thermo Pal Infrared Ear Thermometer, Model no.: ETH-101
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 2, 2011
Received: November 14, 2011

Dear Ms. Reich:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112189

Device Name: **Thermo Pal Infrared Ear Thermometer**
Model no.: **ETH-101**
Digio2 International Co., LTD.

Indications for Use:

The **Thermo Pal Infrared Ear Thermometer (Model no.: ETH-101)** is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC

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

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