K101747

AUG 0 4 2010

510(K) STATEMENT / SUMMARY
AS REQUIRED BY SECTION 807.92(c)

Braun Thermoscan® IRT 4000 Series/Pro 4000 Series
Infra-Red Ear Thermometers with Probe Cover

1. SUBMITTED BY:

CONTACT PERSON: Raj S. Kasbekar

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2. DATE OF SUMMARY PREPARATION: July 12, 2010

3. DEVICE NAME:

	Device	Accessory
Proprietary Name	Braun Thermoscan® Pro 4000 Series/IRT 4000 Series Thermometers	Probe Cover
Common/Usual Name	Infra Red Ear Thermometer	Probe Cover
Classification Name	Clinical Electronic Thermometer	Probe over

Table 1: Device and Accessory Names

4. DEVICE CLASSIFICATION:

Clinical Electronic Thermometer (21CFR 880.2910 Product Code FFL) has been classified under section 513 of the Act as Class II by the General Hospital Devices Panel.

5. DEVICE DESCRIPTION:

IRT/Pro 4000 Series Thermometer:
The Braun Thermoscan® Pro/IRT 4000 series thermometer is a hand held instrument that measures human body temperature through the opening of the auditory canal. It is a single mode ear thermometer that measures the natural thermal infrared radiation emitted from the tympanic membrane and adjacent surfaces with a built-in correction algorithm to compensate the influence of ambient temperature using a heated tip. The difference between the Pro 4000 series thermometer and the IRT 4000 series thermometer is that the Pro 4000 series thermometer is meant for professional use in hospitals and healthcare or professional office

settings, while the IRT 4000 series is meant for home use. There is no change to the thermometer or its manufacture as part of the modification described in this submission.

Probe Cover:
The probe cover (also called as lens filter) is a disposable plastic cover made of a bio-compatible clarified polypropylene material (Pacur) that is dimensionally manufactured to set tolerances so that it can be fitted on the probe tip of the thermometer. The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal to prevent any ear secretions or particulates from being transferred between different people.

The manufacturing site for the probe cover has changed from Braun Ireland Ltd, Ireland to TekPackaging, Huntley, Illinois. In addition alternate materials (same family of plastics) will be used to manufacture the probe covers.

6. STATEMENT OF INTENDED USE / INDICATIONS FOR USE:

The Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometers is indicated for the intermittent measurement and monitoring of human body temperature by consumers of all ages in a home use/professional use environment.

The probe cover is used as a sanitary barrier between the infra red thermometer and the ear canal.

7. SUMMARY OF VERIFICATION ACTIVITIES

In order to show that the probe covers using the new material and made at the new manufacturing site that used the validated process are equivalent to the current probe covers and hence do not affect the temperature measurements taken by the Infra-red thermometer, verification activities were carried out to show that the transmissivity of the probe covers manufactured using the newly validated process were statistically equivalent to the probe covers currently produced (also referred to as the "gold standard samples"). This statistical analysis was carried out by an independent statistical contractor independent from Kaz. Biocompatibility testing in accordance with ISO 10993-1 and Memo G95-1 was also carried out for surface devices with a contact duration of less than 24 hours.

Test Methods

A. To show statistical equivalency, the Black welder method for showing statistical equivalency was used. The gold samples were used on the existing transmissivity test setup up to get a sample mean and standard deviation for the existing probe covers. The gold standard samples were then used on the new transmissivity test machine set up for a total of 1800 data points. A sample mean and standard deviation was then calculated based on these data points. This process was then repeated for samples manufactured at the new manufacturing site using the new material.
B. Biocompatibility Testing: Tests for Cytotoxicity,, Irritation and Sensitization in accordance with ISO 10993-1 and G95-1were carried out at an accredited ISO 17025 certified NAMSA laboratory.

Acceptance Criteria:

A. A tolerance (delta) of $\pm$ 0.01 (10% of the tolerance or range of 0.2 deg C) was deemed adequate to show equivalency between the two data set populations. If the 95% confidence intervals for the difference between the two dataset populations were within these acceptance criteria, the two sets of data can be considered to be equivalent.
B. For Biocompatibility testing, acceptance criteria in accordance with ISO 10993 were chosen and are outlined in the Biocompatibility test reports.

Statistical Analysis

A. For the gold standard samples as well as for the new probe covers made at the new site, ninety five (95) % confidence intervals were calculated for the difference between the two data set populations between the transmissivity test measurements using transmissivity testers at the current site and the new site. Since these 95% confidence intervals were within the chosen acceptance criteria of $\pm$0.01 deg F, the acceptance criteria were met and therefore the data provided evidence of process and device equivalence between current and new probe covers in terms of their transmissivities.
B. For Biocompatibility testing, statistical analysis was carried out in accordance with ISO 10993.

Conclusion

Based on these results, we can conclude that the probe covers made using the new process set up at the new manufacturing site with the new material will not affect the temperature measurements taken by the thermometer.

The new material also passed all the biocompatibility testing carried out as described above..

8. SUBSTANTIAL EQUIVALENCE:

There is no change to the intended use, indications for use, product specifications or technology or operating principle of the Braun Thermoscan® PRO 4000 series and Braun Thermoscan® IRT 4000 series Clinical Infrared Ear Thermometers or that of the probe covers (K031928).

The probe cover is a plastic cover that is used as a sanitary barrier between the infra red thermometer and the ear canal.

The manufacturing site for the probe cover has changed from Braun Ireland Ltd, Ireland to TekPackaging, Huntley, Illinois. In addition alternate materials (same family of plastics) will be used to manufacture the probe covers.

A process validation of the operation at the new manufacturing site and performance testing (biocompatibility testing in accordance with ISO10993-1 and Memo G95-1 for the alternate materials) showed that there are no new questions of safety and effectiveness when compared to the predicate device (probe cover described in K031928). Hence the new probe cover manufactured at the new site is equivalent to the predicate device.

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

Mr. Raj Kasbekar
Vice President, Regulatory Affairs
KAZ USA, Incorporated (A Subsidiary of KAZ Inc.)
250 Turnpike Road
Southborough, Massachusetts 01772

AUG 0 4 2010

Re: K101747
Trade/Device Name: Braun Thermoscan®IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 13, 2010
Received: July 15, 2010

Dear Mr. Kasbekar:

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.

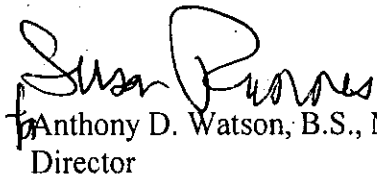
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



for 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

AUG 0 4 2010

510(k) Number (if known): K101747

Device Name: *Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometer*

Indications For Use:

The Braun Thermoscan® IRT 4000 series and Braun Thermoscan® PRO 4000 series Clinical Infrared Ear Thermometers is indicated for the intermittent measurement and monitoring of human body temperature by consumers of all ages in a home use/professional use environment respectively.

The probe cover is used as a sanitary barrier between the infra-red thermometer and the ear canal.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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