3/15/99

K983295

510(k) SUMMARY

Submitter's Name	Braun Thermoscan
Address:	10421 Pacific Center Court San Diego, CA 92121
Phone:	(619) 550-2100
Contact:	Frances E. Harrison
Date of Summary:	September 10, 1998
Name of Device:	Braun Thermoscan ® IRT 3020/3520 Thermometer
Predicate Device:	ThermoScan® Instant Thermometer, Model IR-4000 ThermoScan® Instant Thermometer, Model IR-6000 Genius® First Temp Model 3000A
Device Description:	The Braun Thermoscan IRT 3020/3520 Thermometer is a hand held instrument that measures temperature through the opening of the auditory canal. Operation is based on measuring the natural thermal radiation emitted from the tympanic membrane and adjacent surfaces.
Intended Use:	The Braun Thermoscan IRT 3020/3520 thermometer is intended for the intermittent measurement and monitoring of human body temperature in the home. It is intended for use on people of all ages.
Technological Characteristics:	The Braun Thermoscan thermometers, Models IRT 3020/3520 and IR-6000 have the same general design and incorporate similar materials and components. The Braun Thermoscan IRT 3020/3520 has the same sensor technology as the Genius® First Temp Model 3000A. The primary function of the Braun Thermoscan thermometer, Model is the IRT3020/3520 is the same as the ThermoScan Instant Thermometer, Models IR-4000 and IR-6000 for the measurement of body temperature and raise no new questions of safety and effectiveness.

Braun Thermoscan concludes that the Braun Thermoscan IRT 3020/3520 is substantially equivalent to the ThermoScan IR-4000 and IR-6000.

PRODUCT SPECIFICATIONS:

Model Number	3020, 3520
Technical Characteristics:	
Displayed temperature range:	93.2°F-108°F (34°C-42.2°C)
Operating ambient temperature range:	50°F-104°F (10°C-40°C)
Display resolution:	0.1°F or °C
Temperature scales (user selectable):	°F or °C
Long term storage ranges:	
Temperature	-4 to 122°F (-20 to 50°C)
Humidity (max)	95% noncondensing
Display modes:	EAR (The displayed temperature is the actual measured ear temperature plus a mathematical adjustment to approximate the familiar oral range. However, this is not necessarily the same as an oral temperature taken at the same time.)
Weight (without batteries):	3.5 oz (100g)
Memory recall:	IRT3020, One previous temperature IRT3520, Up to eight temperatures

Accuracy characteristics*:		
Applicable patient ages:	All ages	
Patient temperature range	Error °F	Error °C
96.8°F to 102°F (36 to 39°C)	± 0.4	± 0.2
Outside this range	± 0.5	± 0.3

*ASTM laboratory accuracy requirements in the display range of 36°C to 39°C (98 to 102 °F) for IR thermometers is ± 0.2°C (± 0.4°C), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ± 0.1°C (± 0.2°F).

This infrared thermometer meets the requirements established in ASTM Standard E1965-98, "Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature". Full responsibility for the conformance of this Product to the standard is assumed by Braun AG, 61476 Kronberg, Germany.

SUMMARY OF TESTING:

Non-Clinical Results

PERFORMANCE TEST	RESULTS
Five Environment Accuracy Test	Pass
Thermometer Operating Life Test (Reliability of keys, switch and probe cover ejector)	Pass
Cleaning Test	Pass
Acoustic Noise test	Pass
ENVIORNMENTAL	RESULTS
Altitude Test	Pass
Electromagnetic Compatibility	Pass

Product performance specifications, features and software were validated.

Clinical Results

A comparison study and clinical repeatability testing was performed on the following four ages groups; 0-3 yrs, 4-10 yrs, 11-65 yrs, and >65 yrs. The comparison study demonstrated that the BraunThermoscan IRT 3020/3520 Thermometer measured ear temperature equivalently to the IR-4000 in all age groups. The clinical repeatability is statistically and clinically acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

Braun AG
C/O Mr. Frances E. Harrison
Braun Thermoscan
10421 Pacific Center Court
San Diego, California 92121

Re: K983295
Trade Name: Braun ThermoScan IRT 3020/3520 One Second Ear Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 18, 1999
Received: September 21, 1999

Dear Mr. Harrison

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,

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: Braun ThermoScan IRT 3020/3520 One Second Ear Thermometer

Indications For Use:

The Braun ThermoScan IRT 3020/3520 One Second Ear Thermometer is intended for the intermittent measurement and monitoring of human body temperature by consumers in the home. It is intended for use on people of all ages.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cuccaro

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983295

Prescription Use____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)