K081788

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510(K) SUMMARY

[as required by 807.92(c)]

DEC 17 2008

1. Identification of the Device:

   -Proprietary-Trade Name: "Infrared Ear Thermometer (InnoTherm ICT-100, InnoTherm ICT-200)" INNOCHIPS TECHNOLOGY Co., Ltd.
   -Classification Name thermometer, electronic, clinical, Product Code: FLL
   -Common/Usual Name: Clinical Electronic Thermometer / Infrared Ear Thermometer
2. Equivalent legally marketed device:

   This product is similar in design and identical in function to the K011059 / INFARED EAR THERMOMETER, MODEL TH8 SERIES / RADIANT INNOVATION, INC.

3. Indications for Use (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.

4. Description of the device:

   Infrared Ear Thermometer offers easy, safe, accurate and fast temperature measurement in the ear. Temperature is more accurate core body temperature than other site of the body, since the eardrum shares blood vessels with the temperature control center in the brain (hypothalamus). Therefore, variations in body temperature are reflected sooner and more accurately in the ear than at the other sites on the body.
   Infrared Ear Thermometer is more convenient and safer than an oral thermometer, as it is unaffected by factors such as talking, eating, drinking and smoking.

5. Safety and Effectiveness, comparison to predicate device:

	Infrared Ear Thermometer (InnoTherm ICT-100, InnoTherm ICT-200)	**RII INFRARED EAR THERMOMETER, MODELS TH8 SERIES (K011059)**
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.	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.

Measurement temp range	32.0 ~ 43.0℃ (89.6 ~ 109.4°F)	34.0 ~ 42.2℃ (93.2 ~ 108°F)
Ambient range	16.0 ~ 40.0℃ (93.2 ~ 108°F)	10 ~ 40℃ (50 ~ 104°F)
Storage range	-10 ~ 41℃ (14 ~ 105.8°F)	-20 ~ 50℃ (-4 ~ 122°F)
Display type	LCD	LCD
Activation	Scan button	Scan button
Battery type	CR2032 * 1 pcs	CR2032 * 1pcs
Classification	thermometer, electronic, clinical (Class II), 21 CFR 880.2910	thermometer, electronic, clinical (Class II), 21 CFR 880.2910

6. Testing information and Conclusion

In all material respects, the "Infrared Ear Thermometer (InnoTherm ICT-100, InnoTherm ICT-200)" is substantially equivalent to RII INFRARED EAR THERMOMETER, MODELS TH8 SERIES (K011059) RADIANT INNOVATION, INC. Testing was performed according to 'Harmonized Standard and ASTM'. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innochips Technology Company, Limited
C/O Mr. Brandon Choi
General Manager
PATS Corporation
49 Candlewood Way
Buena Park, California 90621

DEC 17 2008

Re: K081788
Trade/Device Name: Infrared Ear Thermometer (InnoTherm ICT-100, InnoTherm ICT-200)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 21, 2008
Received: November 21, 2008

Dear Mr. Choi:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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):

Device Name: Infrared Ear Thermometer (InnoTherm ICT-100, InnoTherm ICT-200)

Indications for use:

Infrared Ear Thermometer (InnoTherm ICT-100 and InnoTherm ICT-200) is intended for an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X__ (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

510(k) Number: K081788