K111703

MAR 2 9 2012

510(K) SUMMARY

[as required by 807.92(c)]

1. Identification of the Device:

   -Proprietary-Trade Name: Infrared Thermometer (FT-F11, FT-F21, FT-F31, FT-F41)" / Fudakang Industrial 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 K081788 / INFARED EAR THERMOMETER, MODEL: InnoTherm ICT-100 / INNOCHIPS TECHNOLOGY Co., Ltd. and THE INFRARED FOREHEAD THERMOMETER, MODEL FS-300&301(K101912) / HUBDIC CO., LTD

3. Indications for Use (intended use):

   Infrared Thermometer (FT-F11) 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.

   Infrared Thermometer, (FT-F21, FT-F31, FT-F41) is intended for intermittent measurement of human body temperature in people of all ages.

4. Description of the device:

   This infrared Ear Thermometer measure the temperature. It's from the ear canal which can be got more quickly and accurate the human body temperature.

   This product has the following advantages:

   1). Easy to Clean& Probe cover Free.
   2). High speed & Accuracy scan the reading of temperature.
   3). Conveniency, Only one key operation.
   4). Automatic display last memorized measuring temperature. When do you turn on the power.

5. Safety and Effectiveness, comparison to predicate device:

	Infrared Ear Thermometer (InnoTherm ICT-100, InnoTherm ICT-200) (K081788)	THE INFRARED FOREHEAD THERMOMETER, MODEL FS-	**Infrared Thermometer (FT-F11, FT-F21, FT-F31, FT-F41)**

		300&301(K101912)	
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 Infrared Forehead Thermometer, FS-300&301 is intended for intermittent measurement of human body temperature in people of all ages.	Infrared Thermometer (FT-F11) 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. Infrared Thermometer, (FT-F21, FT-F31, FT-F41) is intended for intermittent measurement of human body temperature in people of all ages..
Measurement temp range	32.0 ~ 43.0℃ (89.6 ~ 109.4°F)	34 ~ 42.5℃	34℃ - 43℃
Ambient range	16.0 ~ 40.0℃ (93.2 ~ 108°F)	15 ~ 40℃	10.0℃-40.0℃
Storage range	-10 ~ 41℃ (14 ~ 105.8°F)	-20 ~ 50℃	-25.0℃-55.0℃
Display type	LCD	LCD	LCD
Activation	Scan button	Scan button	Scan button
Battery type	CR2032 * 1 pcs	Two 1.5V AAA type batteries	Two 1.5V AAA type batteries
Classification	thermometer, electronic, clinical (Class II), 21 CFR 880.2910	thermometer, electronic, clinical (Class II), 21	thermometer, electronic, clinical (Class II), 21 CFR 880.2910

6. Testing information and Conclusion

In all material respects, the "Infrared Thermometer (FT-F11, FT-F21, FT-F31, FT-F41)" is substantially equivalent to Infrared Ear Thermometer (InnoTherm ICT-100, InnoTherm ICT-200) (K081788) INNOCHIPS TECHNOLOGY Co., Ltd. and THE INFRARED FOREHEAD THERMOMETER, MODEL FS-300&301(K101912) / HUBDIC CO., LTD. Testing was performed according to 'Harmonized Standard'. Test results support the conclusion that actual device performance satisfies the design intent.

- Contact person

NO.8 Yinhe Road ,Yuanjiangyuan Management one, Changping Town, Dongguan ,Guangdong, China.
Tel: +86-769-81098181 Fax: +86-769-81098187
Contact person: Bob Yu / President

- Date Prepared: April 2011

- Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence:

The safe and effective performance of the device has been non-clinically and clinically established through comparative testing with market-cleared devices. Infrared Thermometer (FT-F11, FT-F21, FT-F31, FT-F41) safety has been checked and validated by CHINA CEPREI (SICHUAN) LABORATORY. The clinical and bench tests* demonstrated its accuracy and effectiveness.

- Non clinical
EN 60601-1:2006 on 26th July 2010
EN 60601-1-2:2007 on 21st July 2010
EN 12470-5:2003 on 27th July 2010
- Clinical
ASTM E 1965 on 19th Sep 2010

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

Fudakang Industrial Company Limited
C/O Mr. Daniel Nam
General Manager
PATS Corporation
205 South Broadway, Suite 718
Los Angeles, California 90012

MAR 2 9 2012

Re: K111703
Trade/Device Name: Infrared Thermometer (FT-F11, FT-F21, FT-F31, FT-F41)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 15, 2012
Received: March 21, 2012

Dear Mr. Nam:

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):

Device Name: Infrared Thermometer (FT-F11, FT-F21, FT-F31, FT-F41)

Indications for use: Infrared Thermometer (FT-F11) 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.

Infrared Thermometer, (FT-F21, FT-F31, FT-F41) is intended for intermittent measurement of human body temperature in people of all ages.

Federal law restricts this device to sale on or by the order of a licensed practitioner.

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)

RLH C Chyan 3/29/12

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

510(k) Number: K111703