OCT 2 6 2005

K052849 (1 of 2)

510(K) SUMMARY

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

1.0 Submitter's Name: FAMIDOC TECHNOLOGY CO., LTD.

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Contact: Mr. Steeljin,

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Jason@famidoc.com

2.0 Device Name: Infrared Thermometer

Model: FDIR-V1

Classification Name: Clinical Electronic Thermometer

3.0 Classification: Class II

4.0 Predicate Device Information:

AVITA TS8 Series IR Ear/Forehead Thermometer.
Model NO.: TS-802 3 in 1 Ear/Forehead/Room Thermometer for the TS8 Series.
It's 510(k) number is K031503.

5.0 Device Description:

Infrared Thermometer Model: FDIR-V1 is a hand-held, reusable, battery operated, maximum device that can measures human body temperature by two ways.

1. on forehead, the skin temperature on one's forehead.
2. in ear, the tympanic temperature in one's ear.

The operation principle is based on Infrared Sensor technology. IR Sensor can putout different signal when measuring different object temperature or in different ambient temperature, an ASIC can turn the

signal from IR Sensor to a digital value and display it by LCD.

6.0 Intended Use:

Infrared Thermometer Model: FDIR-V1 is intended for the intermittent measurement and monitoring of human body temperature, by consumers in the home.

7.0 Performance Summary

The device conforms to applicable standards included ASTM E1965-98, EN 12470-5: 2003, IEC 60601-1 and IEC 60601-1-2 requirements.

8.0 Comparison to Predicate Devices and conclusions

Our Infrared Thermometer Model FDIR-V1 is substantially equivalent to AVITA 3 in 1 Ear/Forehead/Room Thermometer for the TS8 Series Model TS-802, It's 510(k) number is K031503.
The two device are very similar in design principle, intended use, functions, material and the adopting applicable standards.
Only their outlook and some parameter such as measurement range, battery life are different. moreover, tests in this submission provide demonstrate these small difference do not raise and new questions of safety or effectiveness.
Conclusions: the Infrared Thermometer Model FDIR-V1 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2005

Famidoc Technology Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
Laboratory and Testing
2600 NW Lake Road
Camas, Washington 98607-8542

Re: K052849
Trade/Device Name: INFRARED THERMOMETER, FDIR-VI
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 5, 2005
Received: October 11, 2005

Dear Mr. Mouser:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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 K452849

510(k) Number (if known):

Device Name: Infrared Thermometer

Indications for Use:

The device is intended for the intermittent measurement and monitoring of human body temperature, by consumers in the home.

Prescription Use ________ AND/OR Over-The-Counter Use ___X___
(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)

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

510(k) Number: K452849