

Chapter 13 510(K) Summary

510(K) SUMMARY

NOV - 1 2007

Famidoc Digital Clinical Thermometer FDTH-V0-1, FDTH-V0-2, FDTH-V0-3, FDTH-V0-4

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

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

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Date October 11, 2007

2.0 Device Name: Famidoc digital clinical thermometer

Model: FDTH-V0-1, FDTH-V0-2, FDTH-V0-3,
FDTH-V0-4

Classification Name: Clinical Electronic Thermometer

3.0 Classification: Class II

4.0 Predicate Device Information:

Atherm digital clinical thermometer
Model: ACT 2000.
It's 510(K) number is K010238

5.0 Device Description:

Famidoc Digital Clinical Thermometer (model FDTH-V0-1, FDTH-V0-2, FDTH-V0-3, FDTH-V0-4) are hand-held, reusable, battery operated, maximum device that can measures human body temperature.

K472641 (P20F3)

Models FDTH-V0-1, FDTH-V0-2, FDTH-V0-3, FDTH-V0-4 have the same indication for use. the difference points are their shapes, waterproof function and measurement speed.

The operation principle is based on thermistor and ASIC technology, a thermistor using as temperature sensor, the sensor's signal is then calculated and displayed by an ASIC. The digital thermometer comprises a thermistor for temperature sensing, a reference resistor for comparing the resistance of the thermistor, a buzzer for sounding effect, an ASIC and a LCD for calculating and displaying the target temperature digitally which the thermistor is immersed.

6.0 Intended Use:

Famidoc Digital Clinical Thermometer Model FDTH-V0-1, FDTH-V0-2, FDTH-V0-3, FDTH-V0-4 are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home. It is used alone for human beings at all ages.

7.0 Measurement Type:

There are three measurement types to use our thermometer.

Axillary measurement, Oral measurement and rectal measurement, when used under the Axillary, it directly contacts body skin. For oral or rectum use, it directly contacts membrane tissue.

8.0 Performance Data:

The devices meet the ASTM Standard Specification for Electronic Thermometer for intermittent Determination of Patient Temperature (ASTM E1112-00), as well as IEC 60601-1 and IEC 60601-1-2 requirements. Bench testing confirmed accuracy, precision and repeatability measurements specified in the labeling. For all body contacting materials, analysis is made that the identical materials have been used in other legally marketed devices under the same use conditions (see Chapter 8 Safety and Effectiveness Evaluation and Risk Analysis, Chapter 10 Biological Compatibility Report). And we had made clinical tests to prove its repeatability and standard deviation are accord with the demand of EN 12470-3:2000 when applied human.

K072641 (P.30A3)

9.0 Comparison to Predicate Devices and conclusions

Our Digital Clinical Thermometer Model FDTH-V0-1, FDTH-V0-2, FDTH-V0-3, FDTH-V0-4 are substantially equivalent to Actherm digital clinical thermometer Model: ACT 2000, It's 510(k) number is K010238.

They are very similar in design principle, intended use, functions, material and the adopting applicable standards.

Only their outlook and some parameter such as measurement speed, battery life is different. Moreover, tests in this submission provide demonstrate these small difference do not raise and new questions of safety or effectiveness.

Conclusions: the Famidoc Digital Clinical Thermometer Model FDTH-V0-1, FDTH-V0-2, FDTH-V0-3, FDTH-V0-4 are substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Famidoc Technology Company, Limited
C/O Mr. Tomas Huang
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

Re: K072641

Trade/Device Name: Famidoc Digital Clinical Thermometer FDTH-VO-1,
FDTH-VO-2, FDTH-VO-3, FDTH-VO-4

Regulation Number: 880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

Dated: October 17, 2007

Received: October 18, 2007

Dear Mr. Huang:

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

510(k) Number (if known): K072641

Device Name: Famidoc Digital Clinical Thermometer

Indications for Use:

Famidoc Digital Clinical Thermometers are intended for the measurement and monitoring of human body temperature, by doctor or consumers in the hospital or home. It is used alone for human beings at all ages.

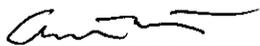
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓
(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)



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

510(k) Number: K072641