

K101387

Fudakang - Thermometer - 510(K) Files: Section 5

510(K) SUMMARY

AUG 03 2010

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 Information

Establishment Registration Name:

Fudakang Industrial Co., Ltd

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2.0 Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Thermometer, electronic
Trade Name:	Digital Thermometer
Model:	BT-A11CN, BT-A21CN, BT-A41CN
Classification name:	Thermometer, electronic, clinical
Review Panel:	General Hospital
Product Code:	FLL
Regulation Class:	II
Regulation Number:	880.2910

3.0 Predicate Device Information

Sponsor:	Famidoc Technology Co., Ltd.
Device:	Famidoc Digital Clinical Thermometer FDTH-V0-1, FDTH-V0-2, FDTH-V0-3, FDTH-V0-4.
510(K) Number:	K072641

4.0 Device description

Fudakang digital thermometers are hand-held, reusable, battery operated. The models include BT-A11CN, BT-A21CN, and BT-A41CN. All the models have the same indication for use. The difference points are their shapes, colors, voice function, and measurement speed.

The operation principle is based on thermosensor and ASIC technology. A thermistor is used as thermosensor. The ASIC gets the sensor's signal from human body, then processes the signal and calculates the result, after that displays the temperature result by a LCD. The digital thermometer comprises a thermistor for getting temperature signal, a reference resistor for comparing the resistance of the thermistor, a buzzer for sounding effect, an ASIC for processing the target temperature digitally, and a LCD for displaying the temperature result.

5.0 Intended Use

Fudakang Digital Thermometers are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home.

6.0 Performance Summary

The devices meet the ASTM Standard Specification for Electronic Thermometer for intermittent Determination of Patient Temperature ASTM E1112-2006, as well

as IEC 60601-1 and IEC 60601-1-2 requirements. The bench test confirmed that the accuracy, precision and repeatability of device are compliance with ASTM E1112-2006 requirements.

The thermometers can be used for axillary, oral and rectal measurement. For axillary use, it directly contacts body skin. For oral or rectum use, it directly contacts membrane tissue. The patient contact materials in the device are made of stainless steel, ABS plastic, and thermoplastic rubber. They are all compliance with ISO10993-1 biocompatibility requirements, and pass the ISO10993-5 and ISO10993-10 tests.

7.0 Comparison to predicate device and conclusion

Compare with predicate device, they are very similar in design principle, intended use, functions, material and the adopting applicable standards. The differences between applicant device and predicate device do not raise and new questions of safety or effectiveness.

1). Indication for use

Famidoc Digital Clinical Thermometer can be used for axillary measurement, oral measurement and rectal measurement. Fudakang Digital Thermometers, BT-A11CN, BT-A21CN, BT-A41CN have the same measurement application.

2). Environment conditions

The environment conditions of Fudakang Digital Thermometers are a little different from Famidoc Digital Clinical Thermometer. But they are both compliance with IEC 60601-1 and ASTM E1112 requirements. So the difference of environment conditions will not raise any safety or effectiveness issue.

3). Accuracy

The accuracy of subject device is:

95.0 - 102.0°F: +/- 0.2°F

35.0 - 39.0°C: +/- 0.1°C

The rest: +/- 0.2°C

The accuracy of predicate device is:

+/- 0.1°C (0.2°F) for whole range

Although there is a little difference, but the subject device accuracy is compliance with ASTM E 1112 requirements. So the difference of accuracy will not raise any safety or effectiveness issue.

4). Response time

The Subject Device is 60s. The Predicate Device is 30s.
The Response time of Fudakang Thermometers is a little different from Famidoc Digital Clinical Thermometer. They are all compliance with IEC 60601-1 and ASTM E 1112 requirements. The difference of Response time will not raise any safety or effectiveness issue.

Conclusions: Fudakang Digital Clinical Thermometers, model: BT-A11CN, BT-A21CN, BT-A41CN are substantially equivalent to the predicate devices.

8.0 Submission prepared date: March 23, 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 Industries Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

AUG 03 2010

Re: K101387

Trade/Device Name: Digital Thermometer, Models BT-A11CN, BT-A21CN, BT-A41CN

Regulation Number: 21 CFR 880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

Dated: July 9, 2010

Received: July 19, 2010

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. 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.

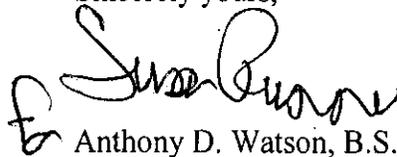
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Statement of Indications for Use

510(k) Number (if known):

K101387

Device Name: Digital Thermometer

Models: BT-A11CN, BT-A21CN, BT-A41CN

AUG 03 2010

Indications For Use:

Fudakang Digital Thermometers are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home.

BT-A11CN, BT-A21CN, BT-A41CN can be used for axillary measurement, oral measurement and rectal measurement.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RL C. [Signature] 8/3/10
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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