K131771

B2. 510(k) Summary

510(K) SUMMARY

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

The Assigned 510(k) number is: _____

1. Submitter Information:

Application Correspondence:
Contact Person: Paul Liu
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New Taipei City, 24888, Taiwan
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OCT 07 2013

Date of submission: June 10, 2013

Applicant:
Company Name: Thermomedics Inc.
Contact Person: Gary J O'Hara
Address: 18310 Calle La Serra
Rancho Santa Fe, CA 92091
Phone: 858 779 1060
Fax: 305 433 5129
E-mail: gohara@thermomedics.com

2. Device name:
Proprietary name: Caregiver Professional Clinical Thermometer
Model no: PRO-TF Series (Model PRO-TF300)
Regulatory information:
   A. Regulation section: 21 CFR 880.2910
   B. Classification: Class II
   C. Product Code: FLL, Clinical electronic thermometer

D. Panel: General Hospital (80)

3. Intended Use:
Caregiver professional Clinical Thermometer is an infrared thermometer intended for the measurement of human body temperature in people of all ages without contact to the body and may be used by medical professionals or by consumers in a home environment.

4. Device Description:
Caregiver Professional Clinical Thermometer (Model PRO-TF300) is characterized by measuring human body temperature from the surface of human skin. It utilizes infrared technology to measure infrared energy emitted from the skin surface when making a temperature measurement.

Substantial Equivalence Information:

A. Predicate device name:
U-RIGHT TD-1240 Thermometer

B. Predicate K number: K113159

C. Comparison with predicate:

Caregiver Professional Clinical Thermometer (Model PRO-TF300) has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- manufactured by the same process

The modifications encompass:

- displayed temperature range

- memory storage capacity
- modification in the physical appearance
- a modification in the user interface
- labeling change due to the modifications

5. Test Principle:
   The thermometer measures temperature by reading infrared radiation emitting from the skin and converts it into a temperature value.

6. Performance Characteristics:
   Caregiver Professional Clinical Thermometer (Model PRO-TF300) was validated by the tests according to ASTM E1965-98.

   A brief description for each test was given in this section. Table 1 lists items of tests related standard complied and format of data presentation.

Table 1. Summary of test

Item	Standard complied	Data presentation	Attachment
Laboratory accuracy	ASTM E1965-98	Measurement error	A3.1
Clinical accuracy	ASTM E1965-98	Clinical bias Clinical repeatability	A3.2
Storage stability	ASTM E1965-98	Measurement error	A3.3
Shock	ASTM E1965-98	Measurement error	A3.4
Cleaning procedure	ASTM E1965-98	Measurement error	A3.5
Safety	IEC 60601-1	Evaluated by SGS	A3.6
Electromagnetic compatibility (EMC)	IEC 60601-1-2	Evaluated by SGS	A3.7

7. Conclusion:
   Based on the information provided in this submission, the Caregiver Professional Clinical Thermometer (Model PRO-TF300) is substantially equivalent to the predicate U-RIGHT TD-1240 Thermometer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 7, 2013

Thermomedics, Incorporated
Mr. Paul Liu
6F, NO. 127, Wugong 2nd Road, Wugu District
New Taipei City
TAIWAN 24888

Re: K131771
Trade/Device Name: Caregiver Professional Clinical Thermometer, PRO-TF Series (Model PRO-TF300)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 6, 2013
Received: September 9, 2013

Dear Mr. Liu:

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 contact 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B1. Indications for Use

Indications for Use

510(k) Number: K131771

Caregiver Professional Clinical Thermometer, PRO-TF Series (Model PRO-TF300)

Indications for Use:

Caregiver professional Clinical Thermometer is an infrared thermometer intended for the measurement of human body temperature in people of all ages without contact to the body and may be used by medical professionals or by consumers in a home environment.

Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
Date: 2013.10.07 10:41:49 -05'00'

Division Sign-Off
Office of Device Evaluation (ODE)
510(k) K131771

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