K121118

JUN 15 2012

Section 11. 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: Pinjung Chen

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   Email: pinjung.chen@taidoc.com.tw

   Date of submission: March 21st, 2012

   Applicant:

   Company Name: FORA Care Inc.

   Contact Person: Sophia Wu

   Address: 810 Lawrence Drive, Suite104, Newbury Park, CA 91320

   Phone: (805) 498-8188

   Fax: (805) 498-7188

   E-mail: sophiawu@foracare.com

2. Device name:

   Proprietary name: FORA ComfortScan Ear Thermometer, model TD-1261A/B

   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:

FORA ComfortScan Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages and for use in the home. It is also available to detect object's surface temperature including human skin.

4. Device Description:

FORA ComfortScan Ear Thermometer is characterized by measuring human body temperature and object's temperature in the ear canal and at the surface, respectively. It utilizes infrared technology to measure either infrared energy emitted from the eardrum and surrounding tissues or the surface radiation of the object when making a temperature measurement. It is able to detect skin temperature (only as a reference) when aimed at the target surface of human body.

Substantial Equivalence Information:

A. Predicate device name:

FORA ComfortScan Ear Thermometer, model TD-1261A/B

B. Predicate K number: K081445

C. Comparison with predicate:

The FORA ComfortScan Ear Thermometer has the following similarities to the predicate device:

- Same intended use.
- Same operating principle.
- Same functions and physical appearance.
- Same fundamental scientific technology.
- Incorporate the same basic circuit design.
- Incorporate the same materials.
- Same shelf life.
- Same user interface and software.
- Packaged using the same materials.
- Manufactured by the same process.

The modifications:

- 510(k) applicant for the device is FORA Care Inc.
- Labeling changes due to the modifications.

5. Test Principle:

   The thermometer measures temperature by reading infrared radiation emitting from the eardrum and surrounding tissues or the surface radiation of the object and converts it into a temperature value.

6. Performance Characteristics:

   The FORA ComfortScan Ear Thermometer was validated by the tests according to ASTM E1965-98 standard and met the requirements of prEN12470-5:2000 standard.

   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	Appendix
Laboratory accuracy	ASTM E1965-98 prEN12470-5	Measurement error	C.1
Clinical accuracy	ASTM E1965-98 prEN12470-5	Clinical bias Clinical repeatability	C.1
Safety	IEC 60601-1	Evaluated by ETC	C.3
Electromagnetic compatibility (EMC)	IEC 60601-1-2	Evaluated by ETC	C.4
Storage stability	ASTM E1965-98	Measurement error	C.5
Cleaning procedure test	ASTM E1965-98 prEN12470-5	Measurement error	C.6
Shock test	ASTM E1965-98	Measurement error	C.7
Displayed temperature	ASTM E1965-98	Measurement error	C.8
Operating range	ASTM E1965-98 prEN12470-5	Measurement error	C.9

7. Conclusion:

   Based on the information provided in this submission, the FORA ComfortScan Ear Thermometer, model TD-1261AB, is substantially equivalent to the predicate FORA ComfortScan Ear Thermometer, model TD-1261AB.

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

JUN 15 2012

FORA Care, Incorporated
C/O Mr. Pinjung Chen
Regulatory Affairs Specialist
Taidoc Technology Corporation
6F, No.127, Wugong 2nd Road, Wugu District
New Taipei City, Taiwan 24888

Re: K121118
Trade/Device Name: FORA ComfortScan Ear Thermometer, Model TD-1261A/B
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 21, 2012
Received: April 12, 2012

Dear Mr. Chen:

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

Section 8. Indications for Use

Indications for Use

510(k) Number:

Device Name: FORA ComfortScan Ear Thermometer, model TD-1261A/B

Indications for Use:

Fora ComfortScan Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for use in the home. It is also available to detect object's surface temperature including human skin.

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)

Division Sign-Off
Office of Device Evaluation (ODE)
510(k) K121118

for RZC June 11, 2012
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121118