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K050463

JUL 27 2005

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and CFR 807.92.

1. Company Information

Company name: TaiDoc Technology Corporation

Address: 4F, No.88, Sec. 1, Kwang-Fu RD.,
San-Chung, Taipei County, Taiwan, R.O.C., 241

Phone: 886-2-6635-8080

FAX: 886-2-6635-5959

2. Device Identification

TaiDoc TD-11 series ear/skin/surface IR thermometer

Model no.:

CLEVER TD-1107 ear/skin/surface IR thermometer

CLEVER TD-1110 ear/skin/surface IR thermometer

3. Predicate Device

AViTA TS-802 3 in 1 Ear/Forehead/Room thermometer (K031503) by AViTA Corporation.

4. Device Description

The TD-1107/TD-1110 ear/skin/surface IR 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. In addition, it is together with an ambient temperature sensor to monitor room temperature. A clock is integrated into the thermometer to provide what time it is.

5. Intended Use

The TD-1107/TD-1110 ear/skin/surface IR thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal in the home. It is also available to detect object's surface

temperature including human skin temperature. It is for use on people of all ages.

6. Comparison to Predicate Device
   The TD-1107/TD-1110 ear/skin/surface IR thermometer is substantially equivalent in intended use, technology characteristics, and performance characteristics to the AViTA TS-802 3 in 1 Ear/Forehead/Room thermometer.

7. Compliance with Consensus Standards
   The TD-1107/TD-1110 ear/skin/surface IR thermometer conformed to consensus standards and other standards that include:
   - *ASTM E1965-98*

   -Standard specification for infrared thermometers for intermittent determination of patient temperature
   - *IEC 60601-1:1988*

   -Medical electrical equipment -part 1 general requirements for safety, 1998; Amendment 1, 1991-11, Amendment 2, 1995-03
   - *IEC 60601-1-2:2001*

   - Medical electrical equipment -part 1 general requirements for safety; electromagnetic compatibility –requirements and tests
   - *EN 1441:1997*

   -Medical device Risk analysis
   - *ISO 13485:2003*

   -Medical devices-Quality management systems-Requirements for regulatory purposes
   - *ISO 15223:2000*

   -Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
   - *ISO 14971:2000*

   -Medical devices-Application of risk management to medical devices

8. Performance Studies
   The clinical and non-clinical studies were conducted to validate the effectiveness of use. The results were compliance to applicable voluntary standards includes ASTM E1965-98, as well as IEC 60601-1 and IEC

60601-1-2 requirements. For clinical results, differences were within clinical acceptability and repeatability was statistically and clinically acceptable.

9. Conclusion

The TD-1107/TD-1110 ear/skin/surface IR thermometer:

- conforms to consensus standards that are applicable to infrared ear thermometers
- has the similar intended use and technological characteristics as the 510(k) predicate device of AViTA model TS-802

Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of the predicate device. Those engineering changes do not (1) affect the intended use or (2) alter the fundamental scientific of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

Mr. Shu-Mei Wu
Project Manager
TaiDoc Technology Corporation
4F, No. 88, Sec. 1, Kwang-Fu Road,
San-Chung, Taipei
CHINA (Taiwan) 241

Re: K050463
Trade/Device Name: TaiDoc TD-11 Series Ear/Skin/Surface IR Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 24, 2005
Received: May 26, 2005

Dear Mr. Wu:

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

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K050463

Indications for Use

510(k) Number: _____

Device Name: TaiDoc TD-11 series ear/skin/surface IR thermometer

Indications for Use:
The device is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages 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 In Vitro Diagnostic Devices (OIVD)

Sheila A. Murphy MD for AD Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K050463