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A. 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: **K101569**

1. Submitter's Identification:

TaiDoc Technology Corporation
3F, 5F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

Correspondence:
Teling Hsu
Regulatory Affairs Specialist
Tel: +886-2-6625-8188
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Prepared date: Jun 2, 2010

2. Device name:

Proprietary name: V-TRUST TD-2202 Portable ECG Recorder, MODEL TD-2202

Regulatory information:

A. Regulation section: 21 CFR 870.2340
B. Classification: Class II
C. Product Code: DPS, electrocardiograph
D. Panel: Cardiovascular

3. Intended Use:

The V-TRUST TD-2202 portable ECG recorder is intended for recording and displaying ECG data of adult patients who are concerned about their heart rhythm. A patient can either equip a five lead-wires ECG cable to take a long term monitoring; or choose to use event reading option when feeling any heart condition occur. This recorder allows the patient to record their ECG data in SD memory card and playback the data for analysis by

a physician or those knowledgeable about ECG morphology, rhythm, and arrhythmia.

The V-TRUST TD-2202 portable ECG recorder can also wirelessly transmit recorded ECG to a Bluetooth-enabled computer.

4. Device Description:

The V-TRUST TD-2202 Portable ECG Recorder provides a long-period recording with multiple channels and transient recording with single channel for individual use. This portable electrocardiograph has a touch screen interface, TFT (Thin Film Transistor)-LCD waveform display, one SD (Secure Digital) memory card insertion port, data transmission via Bluetooth, and 24 hours of continuous recording (in non-compressed format).

5. Substantial Equivalence Information:

   A. Predicate device name and k number:

      - E3-80 Portable ECG Recorder & Analyzer (K071085)
      - HCG-801 portable EGG Monitor (K060766)

   B. Comparison with predicate:

   The V-TRUST TD-2202 Portable ECG Recorder has equivalent technological characteristics and the similar intended use as the predicate devices.

6. Test Principle:

The V-TRUST TD-2202 Portable ECG Recorder uses the same test principle as the predicate devices.

7. Performance Characteristics:

   The bench tests were performed according to IEC 60601-1, 1EC 60601-1-2 Medical and AAMI EC 38, and the results demonstrate that the V-TRUST TD-2202 Portable ECG Recorder conform to the standards and is safe and effective.

8. Conclusion:

   Based on the information provided in this submission, the V-TRUST TD-2202 Portable ECG Recorder is substantially equivalent to the predicate devices.

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

TaiDoc Technology Corporation
c/o Ms. Teling Hsu
Regulatory Affairs Specialist
6F, No. 127, Wugong 2nd Rd., Wugu Township
Taipei County 24888
Taiwan

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Re: K101569
Trade/Device Name: V-TRUST TD-2202 Portable ECG Recorder
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: December 31, 2010
Received: January 3, 2011

Dear Ms. Hsu:

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 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101569

Indications for Use

510(k) Number:K101569

Device Name: V-TRUST TD-2202 Portable ECG Recorder, MODEL TD-2202

Indications for Use:

The V-TRUST TD-2202 portable ECG recorder is intended for recording and displaying ECG data of adult patients who are concerned about their heart rhythm. A patient can either equip a five lead-wires ECG cable to take a long term monitoring; or choose to use event reading option when feeling any heart condition occur. This recorder allows the patient to record their ECG data in SD memory card and playback the data for analysis by a physician or those knowledgeable about ECG morphology, rhythm, and arrhythmia.

The V-TRUST TD-2202 portable ECG recorder can also wirelessly transmit recorded ECG to a Bluetooth-enabled computer.

Prescription Use __X___ AND/OR Over-The-Counter Use ____
(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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101569