NOV 22 2011

Attachment 3

510(K) SUMMARY K 110893

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's Identification:
   VTRUST Medical Business Unit
   TaiDoc Technology Corporation
   3F, 5F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

   Correspondent:
   Erica Li
   Sales Director
   Tel: +886-2-6625-8188 #1172
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   Date of preparation: March 22, 2011

2. Device name:
   Proprietary name: VTRUST FINGER TYPE PULSE OXIMETER

   Regulatory information:
   A. Regulation section: 21 CFR 870.2700 Oximeter
   B. Classification: Class II
   C. Product Code: DQA
   D. Panel: Anesthesiology

3. Intended Use:
   The VTRUST Finger Type Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults.

   This device is indicated for non-invasive spot checking.

4. Device Description:
   The proposed device is a finger type device which is designed for non-invasive spot checking of functional arterial oxygen saturation (SpO_2) and pulse rate for adults based on the principle of spectrophotometry.

   The proposed device utilizes the conventional oximetry technology. The sensor contains a dual light source (red and infrared light-emitting diodes) and photo-detector (photodiode). The photo-detector senses the light signal and the sensor converts this electrical information by use of an algorithm to provide real time values of SpO_2, pulse rate and pulse amplitude.

   The proposed device has approved under water resistant and dust resistant level IP56.

5. Substantial Equivalence Information:
   A. Predicate device name: V-TRUST Handheld Pulse Oximeter
   B. Predicate K number: K101012
   C. Comparison with predicate:

   The proposed device has the following similarities to the predicate device:

   - same operating principle,
   - same oximetry measuring technology,
   - same intended use

   The modifications encompass:

   - Device dimension including PCB layout,
   - Software,

A comparison table that describes detailed similarities and modifications is provided in attachment 2 and it demonstrates that the proposed and the predicated devices are substantially equivalent.

D. Testing

For testing according to the above modification, please see below table

Modification	Validation report	Attachment
Device dimension	Safety, EMC, Biocompatibility	Attachment 4.2-4.4
Software	Software validation	Attachment 4.7
Safety and effectiveness	Risk management, Clinical study, and Consumer study	Attachment 4.1, 4.5, 4.6

According to those reports, it confirmed that the performance, safety and effectiveness of the proposed device are equivalent to the predicate device.

6. Conclusion:

Based on the performance data provided in this submission, the proposed device is substantially equivalent to the predicate with the same effectiveness and safety.

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

Ms. Teling Hsu
Regulatory Affairs Specialist
TaiDoc Technology Corporation
3F, 5F, NO 127 Wugong 2nd Road
Wugu Township
Taipei County
CHINA (TAIWAN) 24888

NOV 22 2011

Re: K 110893
Trade/Device Name: VTRUST Finger Type Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 13, 2011
Received: July 13, 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. 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.

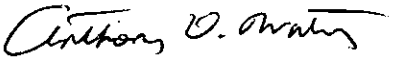
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K110893

Attachment 1

Indications for Use

510(k) Number (if known):

Device Name: VTRUST Finger Type Pulse Oximeter

Indications for Use:

The VTRUST Finger Type Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults.

This device is indicated for non-invasive spot checking.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110893