K101012

DEC 15 2010

Attachment C4

510(k) Summary

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
Address	3F, 5F, No. 127, Wugong 2nd Rd., Wugu Township, Taipei County, 24888, Taiwan
Phone	(+886-2) 6625-8188 ext.1176
FAX	(+886-2) 6625-0288
E-mail	teling.hsu@taidoc.com.tw
Date Prepared	April 2nd, 2010

2. Name of Device

Trade Names	V-TRUST Handheld Pulse Oximeter
Common Names	Oximeter
Product Code	DQA
Classification Panel	Anesthesiology
Regulations	Class II 21 CFR 870.2700

3. Predicate Device

Trade/Proprietary Name:	503 PULSE OXIMETER
Common/Usual Name:	Oximeter
Submitter	CRITICARE SYSTEMS, INC.
510 (k) Number	K911124

4. Device Description

The V-TRUST Handheld Pulse Oximeter is a light weight, portable and non-invasive pulse oximeter designed for use in measuring and displaying functional arterial oxygen saturation and pulse rate for adults during no motion based on the principle of spectrophotometry.

The V-TRUST Handheld Pulse Oximeter uses the same fundamental technology with the predicate device, 503 Pulse Oximeter. The SpO_2 and pulse rate software algorithms,

interference-filtering software, and alarming system are identical to the software in the legally marketed predicate device cleared under K911124, with minor changes that do not raise new questions of safety or efficacy.

The V-TRUST Handheld Pulse Oximeter is allowed to link individual Solaris Compatible Reusable Adult SpO_2 Finger Sensor (k061931) only. Solaris finger sensors are electro-optical sensors which function without skin penetration, electrical contact, or heat transfer. The sensors use optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter device.

5. Intended Use

The V-TRUST Handheld 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 with reusable SpO_2 sensor accessories is indicated for non-invasive spot checking or continuous monitoring.

6. Comparisons to the Predicate Device

The V-TRUST Handheld Pulse Oximeter has the following technological characteristics compared with the predicate device, 503 Pulse Oximeter (K911124):

Description	Proposed Device	Predicate Device
	V-TRUST Handheld Pulse Oximeter	503 Pulse Oximeter
Intended patient population	Adult	Adult
Intended application site	Finger	Finger
Performance specifications	Subject who are well perfused during no motion	Subject who are well perfused during no motion
Detection mode	Continuous monitoring or spot checking	Continuous monitoring or spot checking
Display	LED (light-emitting diode)	LED (light-emitting diode)
SpO2 measurement range	0% to 100%	1% to 99%
SpO2 accuracy	70% to 100%: within ±2%	70% to 99%: within ±2%
Pulse rate measurement range	30 to 250 BPM	20 to 300 BPM

Pulse rate accuracy	±1bpm	±1bpm or ±1%, whichever is greater
Power button	Yes	Yes
SpO2 % display	Yes	Yes
Pulse amplitude indicator	Yes	Yes
Pulse rate display	Yes	Yes
Low battery indicator	Yes	Yes
Sensor error indicator	Yes	Yes
Sensor connector port	Yes	Yes
Alarm	Yes	Yes
Storage condition	-4°F to 122°F (-20°C to 50°C), below 95%, non-condensing	-4°F to 131°F (-20°C to 55 °C), below 95%, non-condensing
Operating condition	32°F to 113°F (0°C to 45°C)	50°F to 104°F (10°C to 40°C)

7. Performance Studies

The clinical test included 10 healthy subjects (5 males and 5 females) aged 25-44 years old for the hypoxia study.SpO2 and heart rate accuracy were determined by testing on subjects during no motion over the range of 70% to 100% SpO2 against the artery blood gas (ABG) analyzer in hospital and the predicate device 503 Pulse Oximeter.

The study was performed in accordance with ISO 9919:2005. The SpO2 Arms of the study was equal to or less than the performance test criteria of 2% and the heart rate variation was within +/- 1 bpm as the specifications. The comparison between V-TRUST Handheld Pulse Oximeter and the predicate also showed 2% error limit for adults in the SpO2 range of 70% to 100%. Based on the results, V-TRUST pulse oximeter is substantial equivalent to the predicate device.

The consumer study was performed in both clinical and home environments and the device was used by healthcare professionals and lay users. The results demonstrate that the oximeter is suitable for use as intended SpO2 and heart rate accuracy.

The V-TRUST Handheld Pulse Oximeter meets the requirements of IEC/EN 60601-1:1995, IEC/EN 60601-1-2:2001, ISO 9919: 2005,ISO 10993-5: 1999 and ISO

10993-10: 2002. Software of the proposed device is validated.

The quality system for the Handheld Pulse Oximeter is well documented in the manufacturer's quality management system and conforms to ISO 13485 and ISO 9001.

8. Conclusion

The V-TRUST Handheld Pulse Oximeter demonstrates satisfactory performance and is suitable for its intended use. The V-TRUST Handheld Pulse Oximeter is substantially equivalent to the predicate device 503 Pulse Oximeter.

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

Mr. Teling Hsu
Regulatory Affairs Specialist
TaiDoc Technology Corporation
3F, 5F, No. 127, Wugong 2nd Road
Wugu Township, Taipei County
Taiwan 24888

DEC 15 2010

Re: K101012
Trade/Device Name: V-TRUST Handheld Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 7, 2010
Received: December 10, 2010

Dear Mr. 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

K101012

Indications for Use

510(k) Number:

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Device Name:

V-TRUST Handheld Pulse Oximeter

Indications for Use:

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Prescription Use ___X___ AND/OR Over the Counter Use _____
(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 In Vitro Diagnostic Device Evaluation and Safety (OIVD)

L Schuttner

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K101012

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

510(k) Number: _____