



Food and Drug Administration  
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August 18, 2016

Jiangsu Konsung Bio-Medical Science and Technology Co. Ltd  
Mr. Yu Defeng  
No. 8, Shengchang West Road,  
Danyang Economy Development Zone  
Jiang Su, China

Re: K152091

Trade/Device Name: Fingertip Pulse Oximeter  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: Class II  
Product Code: DQA  
Dated: July 12, 2016  
Received: July 19, 2016

Dear Mr. Defeng:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**Michael J. Ryan -S**

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152091

Device Name

Fingertip Pulse Oximeter

Indications for Use (Describe)

The Fingertip Pulse Oximeter is intended for spot checking in measuring and displaying functional arterial hemoglobin (SpO<sub>2</sub>) and pulse rate of adult and pediatric patients in hospitals, hospital facilities and home healthcare environments.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary

[As required by 21 CFR 807.92]

### 1. Date Prepared [21 CFR807.92 (a) (1)]

August 5th, 2016

### 2. Submitter's Information [21 CFR807.92 (a) (1)]

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### 3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name: Fingertip Pulse Oximeter

Model Name: SONOSAT-F01T,SONOSAT-F02T

Common Name: Pulse Oximeter

Regulatory Classification: 21 CFR 870.2700

Product Code: DQA

Classification Panel: Anesthesiology

Device Class: II

### 4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicates within this submission are as follows:

K142888 Fingertip Pulse Oximeter

### 5. Description of the Device [21 CFR 807.92(a)(4)]

This device is a small, lightweight, portable device intended for use in measuring and displaying functional oxygen saturation of arterial haemoglobin (%SpO2) and pulse rate (PR).The device measures SpO2 and PR with a SpO2 sensor and displays on the OLED after certain further processing.

The device is mainly composed of the motherboard, SpO2 transducer and built-in battery.

The power supply is 3.7V Li-battery and also the subject device can be powered by adapter.

The subject device is not for life-supporting or life-sustaining and it is not an implantable device.

The subject device owns software which has been validated by the manufacturer.

## 6. Indications For Use [21 CFR 807.92(a)(5)]

The Fingertip Pulse Oximeter is intended for spot checking in measuring and displaying functional arterial hemoglobin (SpO<sub>2</sub>) and pulse rate of adult and pediatric patients in hospitals, hospital facilities and home healthcare environments.

## 7. Technological Characteristics [21 CFR 807.92(a)(6)]

The Finger Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is  $662\pm 3$  nm, which is red light; the other is  $890\pm 5$  nm, which is Infrared light. Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO<sub>2</sub>. This equipment mainly composed of the motherboard, SpO<sub>2</sub> transducer and built-in battery.

## 8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

The subject device finger pulse oximeter has taken the Electricity safety, EMC, performance and biocompatibility testing into concern in accordance with Food and Drug Administration related guidance and recognized international standards.

The following is comparison table between subject device and predicate device.

Items	Predicate device	Subject device
	MD300C318T2	SONOSAT-F01T SONOSAT-F02T
Indications for use	The MD300C318T2 is intended for spot checking in measuring and displaying functional arterial hemoglobin (SpO <sub>2</sub> ) and pulse rate. It is intended for adult, adolescent, child and infant users in hospitals, hospital facilities and home healthcare environments.	The Fingertip Pulse Oximeter is intended for spot checking in measuring and displaying functional arterial hemoglobin (SpO <sub>2</sub> ) and pulse rate of adult and pediatric patients in hospitals, hospital facilities and home healthcare environments.
Intended patient	adult, adolescent, child and infant	Adult, pediatric

population		
Intend application site	Finger	Finger
Intended application environment	hospitals, hospital facilities and home healthcare environments.	hospitals, hospital facilities and home healthcare environments.
Measurement Range	SpO <sub>2</sub> 70%-100% Pulse Rate 30 to 235 bpm	SpO <sub>2</sub> 0%-100% Pulse Rate 18 to 250 bpm
Accuracy Tolerance	<b>Saturation</b> 70 to 100% ±2% Less than 70%, unspecified  <b>Pulse Rate</b> ±2bpm	<b>Saturation</b> 70 to 100% ±2% Less than 70%, unspecified  <b>Pulse Rate</b> 25bpm~250bpm, ±3bpm
Resolution	SpO <sub>2</sub> 1% Pulse Rate 1 bpm	SpO <sub>2</sub> 1% Pulse Rate 1 bpm
General requirement	Compliance with IEC60601-1	Compliance with IEC60601-1
Special requirement	Compliance with ISO 80601-2-61	Compliance with ISO 80601-2-61
	Compliance with IEC 60601-1-11	Compliance with IEC 60601-1-11
EMC	Compliance with IEC60601-1-2	Compliance with IEC60601-1-2
Biocompatibility	Compliance with ISO10993-1	Compliance with ISO10993-1
Regulation No.	CFR 870.2700	CFR 870.2700
Product code	DQA	DQA
Classificaiton	II	II
Type of protection	Internally powered	Internally powered
Power Type	battery	battery
Degree of protection	Type BF - Applied part	Type BF - Applied part
Principles of Sensor	pulse oximetry sensors adopts non-invasive double wavelength to measure SpO <sub>2</sub> and PR	pulse oximetry sensors adopts non-invasive double wavelength to measure SpO <sub>2</sub> and PR
Tests conducted	Cytotoxicity, Delayed Contact Sensitization, Skin Irritation	Cytotoxicity, Delayed Contact Sensitization, Skin Irritation
Result of tests	No toxicity to cells, No delayed contact sensitization, No irritation to skin	No toxicity to cells, No delayed contact sensitization, No irritation to skin
Description	OLED	OLED
Pleth waveform	YES	YES
Lagre Numeric	YES	YES
SpO <sub>2</sub>	YES	YES
PR	YES	YES
Level of concern	Moderate	Moderate

The Indications for Use is a little different in intended patient population, the clinical study data shows that the proposed device could be used effectively in the patient population we claimed. Therefore, this difference is not critical to the intended use of the proposed device and the difference doesn't affect the safety and effectiveness of the device when used as labeled.

Based on the comparison mentioned above, Test data and report information included in this submission, we demonstrate that the subjected device is substantially equivalent to the predicate device.

## **9. Functional and safety testing**

### **Non-Clinical Test**

The Fingertip Pulse Oximeter models SONOSAT-F01T,SONOSAT-F02T is tested in accordance with both mandatory and voluntary standards, including:

IEC 60601-1:2005+Corr.1 (2006)+Corr.2(2007) Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007/AC:2010 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility

IEC 60601-1-11:2010 medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

The Software Validation is in compliance with FDA Guidance to Compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO10993. “Biological Evaluation of Medical Devices”.

### **Clinical Test**

The clinical evaluation was conducted and the result of Finger Type Pulse Oximeter is in compliance with the criteria of ISO 80601-2-61:2011 standard and FDA guidance - “Pulse Oximeter Premarket Notification Submissions” . The functional oxygen saturation (SpO<sub>2</sub>) measurement has been validated on a total of 24 healthy adult male and female volunteers with 2 white people, 7 black people, and 15 yellow-skin people in the range of 70% to 100%.

The SpO<sub>2</sub> accuracy result showed that the root-mean-square (Arms) value of the SONOSAT-F01T and SONOSAT-F02T Fingertip Pulse Oximeter is  $\pm 2\%$  with the saturations from 70% to 100%.

## **10. Conclusion [21 CFR 807.92(b) (3)]**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Jiangsu Konsung Bio-Medical Science And Technology Co.,Ltd concludes that Fingertip Pulse Oximeter models SONOSAT-F01T and SONOSAT-F02T is substantially equivalent to predicate devices.