December 2, 2019

Shenzhen Viatom Technology Co., Ltd.
℅ Vaibhav Rajal
Official Correspondent for Shenzhen Viatom Technology Co., Ltd
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K191088
Trade/Device Name: Oxiband (Checkme) O2 Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: October 31, 2019
Received: November 1, 2019

Dear Vaibhav Rajal:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191088

Device Name
Oxiband (Checkme) O2 Pulse Oximeter

Indications for Use *(Describe)*
The Oxiband Pulse Oximeter is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/ or continuous data collection, and not continuous monitoring. It can be used in sleep labs, long-term care, hospitals and home use.

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

1. Submitter's Identification:

Applicant: Establishment Registration Number: 3011200896
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Date Prepared: November 25, 2019

2. Name of the Device:

Device Common Name: Pulse Oximeter
Device Trade Name: Oxiband (Checkme) O_2 Pulse Oximeter
Model: Oxiband
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA

3. Predicate Device information:

3.1 Primary Predicate Device

510(k) Number: K172366
Trade/ Device Name: Wrist Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter

Regulatory Class: II
Product Code: DQA
Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

3.2 Reference Predicate Device

510(k) Number: K150869
Trade/ Device Name: Checkme Pro Health Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: II
Product Code: MWI
Manufacturer: Shenzhen Viatom Technology Co., Ltd.

4. Device Description:

The Oxiband (Checkme) O2 Pulse Oximter is a lightweight, portable health wrist oximeter for use in sleep labs, long-term care, hospitals and home use. The device indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/ or continuous data collection, and not continuous monitoring.

The data and results provided by this device are for pre-check screening purpose only and cannot be directly used for diagnostic or treatment.

The device consists of main unit, SpO_2 sensor, wristband and charging cable. The main unit is mainly composed of MCU, power management circuit, SpO_2 measurement circuit, display control circuit, etc.

The device is powered by an internal battery. The device is not for life supporting or life sustaining, not for implant. The device or sensor is not sterile, the sensor does not need sterilization, and the sensor is reusable but does not need re-sterilization since it is not sterile. The device is for prescription. The device does not contain drug or biological products.

5. Indications for Use/ Intended Use:

The Oxiband Pulse Oximeter is a wrist pulse oximeter indicated for use in measuring, displaying, storing, and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/or continuous data collection, and not continuous monitoring. It can be used in sleep labs, long-term care, hospitals and home use.

6.Comparison to the 510(k) Cleared Devices (Predicate Devices):

Characteristics	Subject Device	Primary Predicate Device	Reference Predicate Device	Substantial Equivalence or Difference
Name of the device	Oxiband (Checkme) O2 Pulse Oximeter	Wrist Pulse Oximeter MD300W314B4	Health Monitor Checkme Pro	Substantially Equivalent.
Manufacturer	Shenzhen Viatom Technology Co., Ltd	Beijing Choice Electronic Technology Co., Ltd.	Shenzhen Viatom Technology Co., Ltd	Substantially Equivalent.
510(K) Number	K191088	K172366	K150869	Substantially Equivalent.
Product code	21 CFR 870.2700, DQA	21 CFR 870.2700, DQA	21 CFR 870.2300, MWI Secondary product codes: 21 CFR 870.2700, DQA 21 CFR 870.2340, DPS 21 CFR 880.2910, FLL 21 CFR 870.2300, DRT	Substantially Equivalent.
Classification	II	II	II	Substantially Equivalent.
Indication for Use	The Oxiband Pulse Oximeter is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It	The Wrist Pulse Oximeter is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, adolescent, child and infant patients. It is	The Checkme Pro Health Monitor is intended to be used for measuring, displaying, reviewing and storing of ECG (adults only), oxygen saturation and pulse rate (adults only for continuous data collection and recording, adults and	**Compared with Primary Predicate Device:** Both the subject device and the primary predicate device have same IFU including measuring, displaying, storing and transmitting of pulse oxygen saturation

	is intended for spot-check and/ or continuous data collection, and not continuous monitoring. It can be used in sleep labs, long-term care, hospitals and home use.	intended for spot-check and/ or data collection, recording and transmitting. It can be used in sleep labs, long-term care, hospitals and home use.	pediatrics for spot-checking) and temperature in the home or in healthcare facilities. This device is not intended to substitute for a hospital diagnostic ECG device and not to be used on patients with implanted cardiac devices, such as pacemakers and/or implanted cardio-defibrillators (ICDs).	(SpO_2) and Pulse Rate. Both the devices are wrist pulse oximeter. The subject device is used for adult patients whereas the predicate device is used in a wider range of patient population like adult, adolescent, child and infant patients The subject device is used for spot-check or continuous data collection, and not continuous monitoring whereas the primary predicate device is intended for spot-check and/ or data collection. The primary predicate device is also not used for continuous monitoring, so they are substantially equivalent, just

				different expression. **Compared with Reference Predicate Device:** Both the subject device and the reference predicate device have similar function including measuring, displaying, storing and transmitting of pulse oxygen saturation (SpO_2) and Pulse Rate. The reference predicate device is a Cardiac Monitor and has more function (such as ECG and Temperature). The ECG, Temperature and SpO_2 are separate function in reference predicate device, so the ECG and Temperature functions do not affect the SpO_2 and

				Pulse Rate accuracy, the differences will not raise new questions of safety and effectiveness. The subject device is used for spot-check or continuous data collection, and not continuous monitoring in adults whereas the reference predicate device is used in adults only for continuous data collection and recording, adults and pediatrics for spot-checking . The reference predicate device is also not used for continuous monitoring, the subject device is based ob the reference predicate device, so they are substantially equivalent, just different expression.
Rx or OTC	Rx	Rx	Rx	Substantially Equivalent.
Patient type	Adult	Adult, Adolescent, Child and Infant	Adult and pediatric	**Compared with Primary**

				Predicate Device: The subject device is used for adult patients whereas the predicate device is used in a wider range of patient population like adult, adolescent, child and infant patients. The differences does not affect the safety and effectiveness of the subject device. **Compared with Reference Predicate Device:** The subject device is used for adult patients whereas the reference predicate device is used in a wider range of patient types like adults and pediatric patients. tTe differences does not affect the safety and effectiveness

				of the subject device.
Design principle	The subject device design is based on the reference predicate device (Checkme Pro Health Monitor), so they use the same design principle.	The device uses pulse oximetry technology to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger. The sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable mounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).	The device uses pulse oximetry technology to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger. The sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable mounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).	Substantially Equivalent.
Intended application site	Finger	Finger	Finger	Substantially Equivalent.

Work mode	Spot-check and Continuous data collection. The device is not used for continuous monitoring.	Spot-check	Adults for Spot-check and Continuous Pediatrics for Spot-check	**Compared with Primary Predicate Device:** The subject device has spot-check and continuous data collection work mode whereas the primary predicate device just has spot check mode. The subject device continuous work mode is based on the reference predicate device. The subject device meets the requirements of the ISO 80601-2-61 and the FDA Guidance of pulse oximeter-premarket notification issued on March 4, 2013, so the difference doesn't affect the safety and effectiveness of the Subject device. **Compared with Reference**

				Predicate Device: Both the subject device and the predicate device are used in adults for Continuous and Spot-check The subject device and the reference predicate devices are Substantially Equivalent.
Sensor type	External detachable SpO_2 sensor	External detachable SpO_2 sensor	Integrated and External detachable SpO_2 sensor	**Compared with Primary Predicate Device:** Substantially Equivalent. **Compared with Reference Predicate Device:** The reference predicate device uses both integrated and external detachable SpO2 sensors. The subject device external detachable SpO_2 sensor are substantially equivalent to the external detachable SpO_2 sensor of the reference predicate device.

SpO_2 display range	0%-100%	70%-100%	0%-100%	**Compared with Primary Predicate Device:** The subject device has a wider SpO_2 display range of 0% to 100% whereas the predicate device SpO2 range is 70% to 100%. The SpO_2 display range of subject device meets the requirements of the ISO 80601-2-61 and the FDA Guidance of pulse oximeter-premarket notification issued on March 4, 2013, so the difference does not affect the safety and effectiveness of the Subject device. **Compared with Reference Predicate Device:** Substantially Equivalent.
SpO_2 measurement accuracy	70%-100%: ±2% (Arms:1.88) 70%-80%: ±3%	70%-100%: ±2%; ＜70%: unspecified	External sensor 70%-100%: ±2% (Arms:1.88)	**Compared with Primary Predicate Device:**

	80%-90%: ±2% 90%-100%: ±2% 0%-69%: not defined		70%-80%: ±3% 80%-90%: ±2% 90%-100%: ±2% 0%-69%: not defined	The SpO_2 measurement accuracy of the subject device is similar to the SpO2 measurement accuracy for the primary predicate device. The SpO_2 measurement accuracy of subject device meets the requirements of the ISO 80601-2-61, so the difference does not affect the safety and effectiveness of the subject device. **Compared with Reference Predicate Device:** Substantially Equivalent.
SpO_2 resolution	1%	1%	1%	Substantially Equivalent.
Pulse rate measurement range	30 bpm~250 bpm	30 bpm~250 bpm	30 bpm~250 bpm	Substantially Equivalent.
Pulse rate accuracy	±2bpm or ±2% (whichever is greater)	30-99bpm, ±2bpm; 100-250bpm, ±2%	±2bpm or ±2% (whichever is greater)	**Compared with Primary Predicate Device:** The Pulse rate accuracy of subject device is similar to the pulse rate accuracy for

				the predicate device. The pulse rate accuracy of subject device meets the requirements of the ISO 80601-2-61, so the difference does not affect the safety and effectiveness of the subject device. **Compared with Reference Predicate Device:** Substantially Equivalent.
Pulse rate resolution	1bpm	1bpm	1bpm	Substantially Equivalent.
Type, Degree of protection against electric shock	Internal electric power supply; Type BF applied parts.	Internal electric power supply; Type BF applied parts.	Internal electric power supply; Type BF applied parts.	Substantially Equivalent.
Power supply	Lithium rechargeable battery	Lithium rechargeable battery	Lithium rechargeable battery	Substantially Equivalent.
Display screen	OLED	OLED	LCD	**Compared with Primary Predicate Device:** Substantially Equivalent. **Compared with Reference Predicate Device:** The subject device has an

				OLED screen whereas the reference predicate device has an LCD screen. The subject device together with the OLED meets the requirements of the IEC 60601-1, IEC 60601-1-11, ISO 80601-2-61 and IEC 60601-1-2. The difference does not affect the safety and effectiveness of the subject device.
Wireless	Bluetooth	Bluetooth	Bluetooth	Substantially Equivalent.
Storage data	Yes	Yes	Yes	Substantially Equivalent.
Physical dimension(mm)	44 mm (L) × 25 mm (W) × 15 mm (H)	67 mm (L) × 66 mm (W) × 28 mm (H)	88mm (L) x56mm (W) x13mm (H)	**Compared with Primary Predicate Device and Reference Predicate Device:** The physical dimension of subject device is smaller than both, the predicate device and the reference predicate device. The subject device meets the requirements of mechanical

				test in IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-61. The difference does not affect the safety and effectiveness of the Subject device.
Operating temperature	5°C~40°C	5°C~40°C	5°C~45°C	**Compared with Primary Predicate Device:** Substantially Equivalent. **Compared with Reference Predicate Device:** The operating temperature of the subject device is same as the primary predicate device. The reference predicate device has a wider range of operating temperature, which includes the operating temperature range of the subject device. The subject device meets the requirements of the IEC 60601-1, IEC 60601-1-11

				and ISO 80601-2-61. The difference does not affect the safety and effectiveness of the subject device.
Storage and transportation temperature	-25ºC~70ºC	-25ºC~70ºC	-25ºC~70ºC	Substantially Equivalent.
Relative humidity	10%~95%	≤93%, no condensation	10%~95%	**Compared with Primary Predicate Device:** The relative humidity of the subject device is similar to the predicate device and is same as the reference predicate device. The subject meets the requirements of the IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-61, so the difference does not affect the safety and effectiveness of the subject device. **Compared with Reference Predicate Device:** Substantially Equivalent.

Atmospheric pressure	70kPa~106kPa	70kPa~106kPa	70kPa~106kPa	Substantially Equivalent.
Contacting duration	Less than 24h	Less than 24h	Less than 24h	Substantially Equivalent.
Contacting type	Skin surface-contacting	Skin surface-contacting	Skin surface-contacting	Substantially Equivalent.
Biocompatibility of patient contact parts	Comply with ISO10993-1	Comply with ISO10993-1	Comply with ISO10993-1	Substantially Equivalent.

Discussion of Similarities and Differences between Subject and Predicate Devices:

The aforementioned table provides a more detailed comparison of all the characteristic and parameters of the subject device and both the predicate devices. The subject device and the predicate devices all use the same design principle to measure the SpO_2 and Pulse Rate. It is based on the below two basic principles:

- Oxygenated hemoglobin (HbO2) and deoxygenated hemoglobin (Hb) have different absorption characteristic to red and infrared light;
- The light absorption by the blood (Hb and HbO2) is cyclic changing by the periodic pulsations of the arterial blood volume during each heartbeat.

The subject device and both the predicate devices are Substantially Equivalent based on the following similar technological elements:

1. The Subject device is designed based on our own 510k cleared reference Predicate device. The subject device and both the predicate device and reference predicate device are substantially equivalent with respect to theory, critical component, algorithm and technical specification.
2. The subject device and both the predicate device are not used for continuous monitoring.
3. The SpO2 display range for the subject device is broader than the primary predicate device but is identical to the reference predicate device. In addition, SpO2 measurement accuracy over a range of 70% - 100% is identical to subject device and both the predicate device and the reference predicate device.
4. The subject device and both the predicate device and reference predicate device are identical for features like SpO2 resolution, Pulse rate measurement range and the Pulse rate resolution.
5. The subject device and both the predicate device have an internal rechargeable lithium ion polymer battery as the power sources for the devices. The Degree of protection against electric shocks is substantially equivalent too.
6. The subject device and both the predicate device have a Bluetooth feature for transmission and storage of data. All the devices use an external detachable SpO2

sensor for measurement.

7. The operating and storage environment of the Subject device and the Predicate devices are substantially equivalent.
8. Use of patient contact materials which have been tested to compile with the same standard of ISO 10993 for the category of surface device, intact skin contact and limited contact duration (< 24 hours).

The subject device and both the predicate devices are Substantially Equivalent based on the similar technological elements except:

1. The subject device is used for spot-check in adult patients. The measuring mode for the predicate device is spot check in adult, adolescent, child and infant population whereas the reference predicate device has both continuous and spot checking mode. For the reference, predicate device the continuous mode is for adults only and spot-checking mode is for adult and pediatrics.
2. The subject device is used in adult population only, which is within the patient type range of both the predicate devices. The primary predicate device is used in adult, adolescent, child and infant whereas the reference predicate device is used in adult and pediatric population.
3. The Pulse rate accuracy of the subject device is slightly different compared with primary predicate device but is identical to reference predicate device.
4. The subject device has an external detachable sensor, which is substantially equivalent to the primary predicate device external detachable sensor. The reference predicate device uses both the integrated and external detachable SpO2 sensors. The reference predicate device external SpO2 sensor is substantially equivalent to the subject device.
5. The relative humidity of the subject device is slightly different compared with primary predicate device but is identical to reference predicate device
6. The physical dimension of the subject device is different from the physical dimension of the predicate devices.

Based on the aforementioned substantial equivalence discussion between the subject device and the predicate device, these different technological characteristics of Subject device does not raise new risk for the safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating the substantial equivalence of the Oxiband Pulse Oximeter in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft “Reviewer Guidance for Premarket Notification Submissions”, DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements. Accuracy of pulse oximeter, electrical,

mechanical, electromagnetic compatibility, software and biocompatibility testing have been performed on the subject device Pulse Oximeter. The results of the testing demonstrate that the subject device is as safe and as effective, as the legally marketed predicate devices. The following performance data were provided in support of the substantial equivalence determination.

Non-clinical Testing

Non-clinical tests were conducted on the subject pulse oximeter device to verify that the subject device met design specifications was substantially equivalent to the predicates. The test results demonstrated that the subject device complies with electrical safety, electromagnetic compatibility, biocompatibility, software verification and validation, battery safety, home used medical devices safety.

The subject device is considered as skin contacting for duration less than 24 hours. The patient contact materials used by the subject device have been tested to compile with the ISO 10993, and is substantially equivalent to the predicates.

The software for this subject device was considered as a “moderate” level of concern, which is the same as the predicates. Software verification and validation testing were conducted and documentation was provided.

The following testing was conducted to demonstrate substantial equivalence to the predicate device:

Test Standard	Description	Result
ANSI AAMI ES60601-1: 2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	(Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Passed
IEC 60601-1-2 Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Passed
IEC 60601-1-11 Edition 2.0 2015-01	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	Passed
ISO 80601-2-61 First edition 2011-04-01	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	Passed
IEC 62133 Edition 2.0 2012-12	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary	Passed

	cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]	
ISO 10993-1 Fourth edition 2009-10-15	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]	Passed
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Passed
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Passed
ISO 14971 Second Edition 2007-03-01	Medical Devices - Application of Risk Management to medical devices	Passed

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It is concluded that the subject Oxiband Pulse Oximeter device is in compliance with the requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

The predicate device, our own previously 510(k) cleared Checkme Pro Health Monitor (K150869) is in compliance with clinical testing according to ISO14155: 2011 and ISO 80601-2-61: 2011. In addition, the SpO_2 accuracy performance results showed the Checkme Pro Health Monitor with external SpO_2 sensor to have an ARMS of 1.88 during steady state conditions over the range of 70%-100%. The results showed that the SpO_2 accuracy of Checkme Pro Health Monitor claimed under the range of 70%-100% by the manufacturer is in compliance.

At the same time, the Oxiband Pulse Oximeter and Checkme Pro Health Monitor with external SpO_2 sensor shows the equivalence in intended use, sensor design, hardware design, algorithm design and technical specification. The subject and predicate devices are substantially equivalent. The aforementioned information justifies the use of the predicate device Checkme Pro Health Monitor clinical study results for the subject device, Oxiband pulse oximeter. The SpO_2 accuracy of the Oxiband pulse oximeter claimed in the range of 70%-100% by the manufacturer is also in compliance.

9. Software information:

Similar to the predicate device, the software level of concern for the Oxiband pulse oximeter is MODERATE. According to FDA Guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff”, the software validation documentation summarizes the required information for a MODERATE Level of Concern device.

10. Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shenzhen Viatom Technology Co., Ltd. concludes that the subject device Oxiband Pulse Oximeter is as safe and as effective, and thus substantially equivalent, to the predicate device, Checkme Pro Health Monitor.