August 7, 2019

Vita-Course Technologies Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, NanShan Medical Devices Industrial Park,
Nanshan District, Shenzhen, 518067 Cn

Re: K190893
Trade/Device Name: Discovery 1 - Non-invasive Hemodynamic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 9, 2019
Received: May 9, 2019

Dear Kevin Wang:

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,

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular 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)*
K190893

Device Name
Discovery 1 - Non-invasive Hemodynamic Blood Pressure Monitor

Indications for Use *(Describe)*
The Discovery 1 - Non-invasive Hemodynamic Blood Pressure Monitor device is a small, lightweight, handheld, device intended for measuring and display of Blood Pressure trending (systolic and diastolic) and spot-check of Peripheral pulse rate (PPR) and Peripheral pulse wave (PPW). Measurement is performing on capillary finger tip tissue (other than the thumb). The ring finger is the recommended site. The results of each measurement are stored in the system memory. The device is intended for use in the home environment. It is intended to be used by any person aged above 18 years old.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2019/04/01

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Non-invasive Hemodynamic Blood Pressure Monitor
Model	Discovery 1
Common Name	Non-invasive Blood Pressure Monitor
Regulatory Class	Class II
Classification	21CFR §870.1130 / System, measurement, blood-pressure, non-invasive / DXN
Submission type	Traditional 510(K)

4. Predicate Device

By submission of the Traditional 510(k), Vita-Course Technologies Co., Ltd. is requesting clearance for Discovery 1 Non-invasive Hemodynamic Blood Pressure Monitor. It is comparable to the following legally marketed system:

1. Cnoga Medical ACAL, TensorTip™- Non-invasive Hemodynamic Blood Pressure Monitor under K093981.

5. Intended use & Indication for use

The Discovery 1 Non-invasive Hemodynamic Blood Pressure Monitor device is a small, lightweight, handheld, device intended for measuring and display of Blood Pressure trending (systolic and diastolic) and spot-check of Peripheral pulse rate (PPR) and Peripheral pulse wave (PPW). Measurement is performing on capillary

finger tip tissue (other than the thumb). The ring finger is the recommended site. The results of each measurement are stored in the system memory. The device is intended for use in the home environment. It is intended to be used by any person aged above 18 years old.

6. Device Description

Discovery 1 is a portable non-invasive Hemodynamic Blood Pressure Monitor powered by an internal rechargeable lithium polymer battery. It contains a pulse wave probe incorporating two LEDs, which can collect the pulse wave to the device.

7. Principle of Operation

The product is designed to calculate the blood pressure in terms of conduction time of pulse and wave parameters of pulse. This method is proposed based on interdependent characteristics between conduction time of the pulse wave along the arterial as well as characteristic parameters of the pulse wave and arterial pressure. Through the determination of the PPG signal, conduction time of the pulse wave along thee arterial and other correlation variables would be obtained and accordingly the systolic and diastolic pressures of the body are gotten by fitting operation. The pulse rate can be obtained by calculating the pulse wave signal.

8. Comparison to the Predicate Device

The Discovery 1 non-invasive Hemodynamic Blood Pressure Monitor and TensorTip™- Non-invasive Hemodynamic Blood Pressure Monitor (K093981), are identical in purpose, function, core technology and method of operation. Only minor differences exist between the Discovery 1 and predicate, which do not affect the safety or effectiveness of the subject device. Table 1 provides a comparison of the subject and predicate devices.

Table 1: Comparison to Predicate Device

Features	**Subject Device** **Discovery 1 non-invasive Hemodynamic Blood Pressure Monitor**	**Predicate Device K093981** **TensorTip™- Non-invasive Hemodynamic Blood Pressure Monitor**	**Remark**
Indication for use	**The Discovery 1 -** Non-invasive Hemodynamic Blood Pressure Monitor device is a small, lightweight, handheld, device intended for measuring and display of Blood Pressure trending (systolic and diastolic) and spot-check of Peripheral pulse rate (PPR) and Peripheral pulse wave (PPW). Measurement is performing on capillary finger tip tissue (other than the thumb). The ring finger is the recommended site. The results of each measurement are stored in the	The TensorTip - Non-invasive blood pressure trending device is a small, lightweight, handheld, device intended for measuring and display of Blood Pressure trending (systolic and diastolic) and spot-check of Peripheral pulse rate (PPR) and Peripheral pulse wave (PPW). Measurement is performing on capillary fingertip tissue (other than the thumb). The ring finger is the recommended site. The results of each measurement are stored in the system memory. The device is intended	Same

Features	**Subject Device** **Discovery 1 non-invasive Hemodynamic Blood Pressure Monitor**	**Predicate Device K093981** **TensorTip™- Non-invasive Hemodynamic Blood Pressure Monitor**	**Remark**
	system memory. The device is intended for use in the home environment. It is intended to be used by any person aged above 18 years old.	for use in the home environment. It is intended to be used by any person aged above 18 years old.	
Patient Population	>18 years old	>18 years old	Same
Principle of Operation	Hemodynamics	Hemodynamics	Same
Power source	DC adaptor: 5Vd.c., Internal lithium polymer (Li-Pol) battery: 3.7Vd.c., 2200 mAh	DC adaptor: 5Vd.c. Internal Li-Polymer battery: 3.7Vd.c., 740mAh	Different [1)]
Blood pressure	Systolic pressure range: 50 mmHg ~200 mmHg Diastolic pressure range: 40 mmHg ~160 mmHg Accuracy: ±5 mmHg	Systolic pressure range: 90 mmHg ~ 240 mmHg Diastolic pressure range: 30 mmHg ~ 130 mmHg Accuracy: <10%	Different [2)]
Pulse rate	Measurement range: 40 bpm ~ 240 bpm Accuracy: ±2% or ±2 bpm, whichever is greater	Measurement range: 30 bpm ~200 bpm Accuracy: Mean Square Error 0.5digits	Different [3)]
Operating environment	Temperature: 5 °C ~ 45 °C Humidity: 10% ~ 95%	Temperature: 6 °C ~ 45 °C Humidity: 10 ~ 80%	Different [4)]
IP degree	IP22	IP00	Different [5)]
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 81060-2	IEC 60601-1 IEC 60601-1-2 ISO 81060-2	Different [6)]

Justifications for differences between Discovery 1 and the predicate device are shown as below:

Different (1): The capacity of battery is different. However, the battery of subject device is in compliance with IEC 62133: 2012- Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications. Thus, this difference will not raise any safety or effectiveness issue.

Different (2): The measurement range and the accuracy of blood pressure is different. The subject device is compliant with FDA recognized consensus standard ISO 81060-2: 2013. This difference will not raise any safety or effectiveness issue.

Different (3): The measurement range and the accuracy of pulse rate is different. The subject device has been verified all the full claimed range. This difference will not raise any safety or effectiveness issue.

Different (4): The operating environment is minor different. However, the difference will not raise any safety or effectiveness issue.

Different (5): The degree of protection is different and the subject device is better than predicate device. The subject device is compliant with FDA recognized consensus standard IEC 60601-1-11: 2015. This difference will not raise any safety or effectiveness issue.

Different (6): The compliance standards are different. The subject device is compliant with FDA recognized consensus standard IEC 60601-1-11: 2015. This difference will not raise any safety or effectiveness issue.

9. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

NO.	Item	Description
1	Safety	Ensures the device meet the requirements of IEC 60601-1: 2012 and IEC 60601-1-11: 2015
2	EMC	Ensures the temperature probes meet the requirements of IEC 60601-1-2: 2014, IEC 60601-1-11: 2015 clause 12 and ISO 80601-2-61: 2017 clause 201.17 and clause 202
3	Clinical accuracy	ISO 81060-2: 2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

10. Conclusion

It has been shown in this 510(k) submission that the difference between the proposed devices and the predicate devices do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, performance characteristics, and intended use.