January 27, 2022

LotusNine Medical Limited
% Yuhua Chen
Manager
PuHsu Consulting Ltd.
7F., No.272, Jiankang Rd., Zhonghe Dist.
New Taipei City, 235042
Taiwan

Re: K212312/S001
Trade/Device Name: RA-T59 Wrist blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: December 17, 2021
Received: December 29, 2021

Dear Yuhua Chen:

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 and Part 809); 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,

for

LCDR 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)*
K212312

Device Name
RA-T59 Wrist blood pressure monitor

Indications for Use *(Describe)*
The device is a digital monitor for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 inches to 7 1/4 inches (12.8 cm to 18.5 cm).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date prepared: July 15, 2021

1. Submitter's Information

Submission Submitter

Company Name	LotusNine Medical Limited
Address	No. 2, Ln. 223, Sec. 1, Taiping Rd., Tsaotun Township, Nantou County 542007, Taiwan
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Submission Correspondent

Company Name	PuHsu Consulting Ltd.
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Contact Person	Yuhua Chen
Phone	886-965650265
Email	yuhua@puhsuconsult.com

2. Subject Device Information

Proprietary/Trade Name	RA-T59 Wrist blood pressure monitor
Regulation Name	Noninvasive blood pressure measurement system
Regulation Number	870.1130
Product Code	DXN
Device Classification	II
Panel	Cardiovascular

3. Predicate Device Information

510(k) Number	Trade Name	Manufacturer	Type
K131742	Model HEM-6131	Omron Healthcare, Inc.	Predicate Device

4. Device Description

RA-T59 Wrist blood pressure monitor is designed to measure the blood pressure and pulse rate of adults within the range of the designated wrist cuff (12.8 to 18.5 cm). RA-T59 Wrist blood pressure monitor is based on an oscillometric method to measure blood pressure and pulse rate from wrist. The device uses automatic inflation mode. It starts to inflate from 0 mmHg and automatically stops the motor after 25 seconds and quickly deflates, with a steady inflation speed detecting the measurement during inflation. The device utilizes the oscillometric method whereby the electronic pressure sensor converts variation in cuff pressure to electrical signals. The signal from the electronic pressure sensor is conditioned with a circuit before data conversion by an analog-to-digital converter (ADC). The systolic pressure, diastolic pressure, and pulse rate are then calculated in the digital domain. The resulting systolic, diastolic, and pulse-rate measurements are displayed on a LCD and stored in the device's memory.

5. Indications for Use

The device is a digital monitor for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 inches to 7 1/4 inches (12.8 cm to 18.5 cm).

6. Comparison to the Predicate Device

Device	Proposed Device	Predicate Device	Remark
	RA-T59 Wrist blood pressure monitor	Model HEM-6131	
Manufacturer	LotusNine Medical Limited	Omron Healthcare, Inc.	--
510(k) Number	N/A	K131742	--
Product Code	DXN	DXN	Same
Regulation Number	870.1130	870.1130	Same
Indications for Use	The device is a digital monitor for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 inches to 7 1/4 inches (12.8 cm to 18.5 cm).	The device is a digital monitor for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm).	Different (Note 1)

Device	Proposed Device	Predicate Device	Remark
	RA-T59 Wrist blood pressure monitor	Model HEM-6131	
Patient Population	Adult	Adult	Same
Prescriptive	OTC	OTC	Same
Anatomical Site	Wrist	Wrist	Same
Environment of Use	Home	Home	Same
Measuring Method	Oscillometric	Oscillometric	Same
Measurement Range	Systolic blood pressure: 60 - 230 mmHg Diastolic blood pressure: 40 - 130 mmHg Rated range of CUFF pressure: 300 mmHg Pulse: 40 to 180 beats	Pressure: 0-299 mmHg Pulse rate: 40 to 80 bpm	Different (Note 2)
Accuracy or pressure indicator	±3 mmHg or 2% of reading	±3 mmHg or 2% of reading	Same
Accuracy Pulse Rate	±5%	±5%	Same
Inflation and Deflation	Automatic	Automatic	Same
Display Type	LCD	LCD	Same
Power Source	USB type C charging	AAA batteries	Different (Note 3)
Operation Conditions	Temperature: 10°C to 40°C Humidity: 15 to 85% RH	Temperature: 10°C to 40°C Humidity: 15 to 85% RH	Same
Storage Conditions	Temperature: -20°C to 70°C Humidity: 10 to 90% RH	Temperature: -20°C to 60°C Humidity: 10 to 95% RH	Different (Note 4)
Memory	25 Measurements	60 Measurements	Different (Note 5)

Device	Proposed Device	Predicate Device	Remark
	RA-T59 Wrist blood pressure monitor	Model HEM-6131	
Electrical safety	IEC 60601-1-2 IEC60601-1	IEC 60601-1-2 IEC60601-1	Same
Biocompatibility	ISO 10993 series	ISO 10993 series	Same

Comparison

Note 1:

The substantial difference of the intended use is the wrist circumference ranging. The proposed device is narrower than the predicate device. The proposed device was validated according to ISO 80601-2-30 and ISO 81060-2. The performance data can demonstrate this difference does not raise different questions of safety and effectiveness.

Note 2:

The proposed device's systolic and diastolic blood pressure measurement range is restricted from 40 to 230 mmHg. The measuring rang of the proposed device was validated according to ISO 80601-2-30. The different does not raise different questions of safety and effectiveness.

Note 3:

Although the power source is different, IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2, and IEC 62133-2 can demonstrate that the proposed device can maintain the safety and performance when the proposed device is charged. Thus, this difference does not raise different questions of safety and effectiveness.

Note 4:

Compared with the predicate device, the proposed device requires different storage environment. IEC 60601-1-11 test report can demonstrate that the proposed device can maintain the safety and performance within the storage environment. Thus, this difference does not raise different questions of safety and effectiveness.

Note 5:

The memory size of the proposed device is less than the predicate device. The difference is very slight and it will not affect the main function and the intended use of the proposed

device. Therefore, this difference will not raise any safety or effectiveness issue.

7. Performance Testing

Performance testing has been carried out to demonstrate that the proposed device meets the performance specifications for its intend use.

The proposed device was tested to ISO 81060-2: 2018 Non-invasive sphygmomanometers- Part 2: Clinical validation of automated measurement type. The study population consisted of 85 qualified healthy adult subjects. The results of this clinical investigation show that the proposed device fulfills the requirement of ISO 81060-2:2018.

8. Non-Clinical Testing

The subject device has been tested according to the following standards:

A. Safety Test
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-11, 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
- IEC 62133-2, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

B. EMC Test
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

C. Biocompatibility testing
- ISO- 10993, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing
- ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

- ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

D. Performance Test
- IEC 80601-2-30, Medical electrical equipment - Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

E. Software Verification and Validation
- FDA Guidance for the Content of Pre-Market Submission for Software Contained in Medical Devices
- IEC 62304, Medical device software - Software life cycle processes

F. Usability
- IEC 60601-1-6, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1, Medical devices - Application of usability engineering to medical devices.

9. Conclusion

In conclusion, it shows that the proposed device and the predicate device has the same intended use, and the difference in technological features of the proposed devices and the predicate devices do not raise different questions of safety and effectiveness. The result of all testing conducted was found acceptable to support the claim of substantial equivalence.