RWD Life Science Co., Ltd.
℅ Eleanor Wu
Project Engineer
PureID Medical Technology Co., Ltd.
Guangzhou International Biology Island Luoxuan Blvd Guanzhou
Life Science Innovation Center, Bd.A 3301-3310 & 3316-3318
Guangzhou,
China

Re: K233076
Trade/Device Name: Laser Speckle Imaging System (RFLSI CZW)
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular Blood Flow Probe
Regulatory Class: Class II
Product Code: DPT
Dated: September 26, 2023
Received: September 26, 2023

Dear Eleanor Wu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yan Fu -S
Digitally signed by Yan Fu -S
Date: 2024.05.28 13:35:29 -04'00'

for

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233076

Device Name
Laser Speckle Imaging System (RFLSI CZW)

Indications for Use *(Describe)*

The Laser Speckle Imaging System (RFLSI CZW) is intended for blood flow measurements in the micro-circulation. This device is intended for clinical research 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.

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

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510(k) Summary

Prepared on: 2024-05-15

1. Contact Details

Applicant Name: RWD Life Science Co., Ltd.

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Applicant Contact: Mrs. Xuhong Wang

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Correspondent Name: PureID Medical Technology Co., Ltd.

Correspondent Address: Guangzhou International Biology Island Luoxuan Blvd Guangzhou Life Science Innovation Center, Bd.A 3301-3310 & 3316-3318Guangzhou 510000 China

Correspondent Contact Telephone: 0086-1807069013

Correspondent Contact: Mrs. Eleanor Wu

Correspondent Contact Email: raq@cn.purefda.com

2. Device Information

Device Trade Name: Laser Speckle Imaging System (RFLSI CZW)

Common Name: Extravascular blood flow probe

Classification Name: Probe, Blood-Flow, Extravascular

Regulation Number: 870.2120

Product Code: DPT

3. Predicate Devices

Predicate #: K122943

Predicate Trade Name: moorFLPl-2 Full-Field Laser Perfusion lmager

Product Code: DPT

4. Device Description

The Laser Speckle Imaging System (RFLSI CZW) is intended for blood flow measurements in the micro-circulation. This device is intended for clinical research use. It is a measurement tool based on the laser speckle contrast analysis technology and provides real-time blood perfusion information of tissue and organs in a visual and quantitative way. The device is non-patient contacting and does not require the use of contrast agents.

5. Intended Use/Indications for Use

The Laser Speckle Imaging System (RFLSI CZW) is intended for blood flow measurements in the micro-circulation. This device is intended for clinical research use.

6. Technological Comparison to Predicate Device

The subject device Laser Speckle Imaging System (RFLSI CZW) of this Traditional 510(k) uses the same laser speckle technology as that used by the predicate device. Differences in device parameters do not raise new concerns regarding safety and effectiveness. Verification and validation testing for the subject device demonstrate safety and effectiveness. The Laser Speckle Imaging System (RFLSI CZW) has shown to be substantially equivalent to the predicate device for its intended use in a hospital setting or other appropriate clinical environment.

Technological Comparison			
	Subject Device	**Predicate Device**	**Equivalence**
Feature	RFLSI CZW Laser Speckle Imaging System	moorFLPl-2 Full-Field Laser Perfusion Imager	N/A
510(k)#	N/A	K122943	N/A
Common Name	RFLSI CZW Laser Speckle Imaging System	Full-Field Laser Perfusion Imager	N/A
Regulation	21 CFR Part 870.2120	21 CFR Part 870.2120	Same
Product Code	DPT	DPT	Same

Submission & Classification	510(k) Class II		510(k) Class II		Same
Principle	Laser speckle contrast analysis (LASCA)		Laser speckle contrast analysis (LASCA)		Same
Indications for Use	RFLSI CZW Laser Speckle Imaging System is intended for blood flow measurements in the microcirculation. This device is intended for clinical research use.		The moorFLPI-2 Full-Field Laser Perfusion Imager is intended for blood flow measurements in the microcirculation. This device is intended for clinical research use.		Same
Laser Type	Infra-red laser diode	Aiming lasers	Infra-red laser diode	Aiming lasers	Same
Wavelength	785nm ± 10nm	650nm	785nm ± 10nm	650nm	
Measured Parameters	**Flux (Tissue perfusion)** Range: 0-5000 PU Resolution: 1 PU Accuracy: ± 10% **DC (Intensity)** Range: 0~255 AU Accuracy: ± 1 AU Resolution: 1 AU Maximum frame rate: 100 Hz		**Flux (Tissue blood flow)** Range: 0-5000 PU Resolution: 1 PU Accuracy: ± 10% **DC (Light Intensity)** Range: 0~255 AU Accuracy: ± 1 AU Resolution: 1 AU Maximum frame rate: 100 Hz		Same
Measurement Algorithms	Spatial algorithm, Step Mode Spatial algorithm, Sliding Mode Temporal algorithm		Spatial algorithm, Step Mode Spatial algorithm, Sliding Mode Temporal algorithm		Same
Working Distance	10(±0.5)-40(±1.5) cm (distance between the front of the scanning head and the measurement site)		10-38 cm (distance between the scan head and the measurement site)		Different: Slight design differences have no direct effect on the safety and effectiveness of the subject device.
Power Supply	AC mains, 100-240V, 50-60Hz, 30VA		AC mains, 100-230V, 50-60Hz, 30VA		Different: Different supply voltage ranges do not affect the safety and efficacy of the subject device since they still remain within safe and reasonable limits.
PC Connection	USB 3.0 cable		USB 3.0 cable		Same

7. Performance Testing

Performance testing of the device Laser Speckle Imaging System is conducted to evaluate the functionality, efficiency, and overall performance of it. The following tests have demonstrated that the device performs its intended purpose, and it meets the specified requirements and standards:

EMC and Electrical Safety Testing

The device Laser Speckle Imaging System, has undergone rigorous electromagnetic

compatibility testing, including radiated emission, radiated immunity, conducted emission and conducted immunity tests. The test results show that the device conforms to the following performance standards::

- IEC 60601-1-2 Edition 4.0 2014-02 +A1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1:2015+A1: 2012+A2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Safety Testing for Laser Products

Laser safety testing was conducted and shows that the device conforms to following performance standard::

- IEC 60825-1: 2014 Safety of laser products - Part 1: Equipment classification and requirements

Performance Comparison Testing

Comparison tests to verify the substantial performance of the device and the predicate device were conducted, using two kinds of methods: (1) test with laboratory testing model "Flow Model" using a fluid simulator and (2) volunteer test on the human body using post-occlusive reactive hyperemia method, and the results conclude that the device shows comparable performance, safety, and effectiveness to the predicate device.

8. Conclusions

The technological comparison and performance testing demonstrate that the RFLSI CZW Laser Speckle Imaging System is substantially equivalent to its predicate device when used as intended.