September 7, 2022

Beijing Ruicheng Medical Supplies Co., Ltd.
% Mr. Ray Wang
General Manager
No.13 Yanqi Ave, Yanqi Economic Development Zone, Huairou District,
Beijing China,101400

Re: K222034
Trade/Device Name: RightLance Blood Lancing System
Regulation Number: 21 CFR 878.4850
Regulation Name: general & plastic surgery
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: July 7, 2022
Received: July 11, 2022

Dear Mr. 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,

for

Long Chen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222034

Device Name
RightLance Blood Lancing System

Indications for Use *(Describe)*
The RightLance Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm.
The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.
This system is for use only on a single patient in a home setting.
This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

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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K222034-RightLance Blood Lancing System 510(k) Summary

1. Date of Preparation: 09/07/2022
2. Contact Details [21 CFR 807.92(a)(1)]

Applicant (Sponsor) Name: Beijing Ruicheng Medical Supplies Co., Ltd.
Applicant (Sponsor) Address: No.13 Yanqi Ave, Yanqi Economic Development Zone, Huairou District, Beijing China,101400

Applicant Contact #1:
Mr. Ray Wang
Tel: +86-18910677558
Email: information@believe-med.com

Applicant Contact #2:
Ms. Yuechao Li
Tel: +86-18910106615
Email: lily@ruichengmedical.com

3. Proposed Device Name [21 CFR 807.92(a)(2)]

Device Trade Name: RightLance Blood Lancing System.
Common Name: Blood Lancet.
Classification Name: Blood Lancet.
Regulation Name: 878.4850, Class II
Product Code: QRL, QRK

4. Legally Marketed Predicate Device [21 CFR 807.92(a)(3)]

510(k) Number: K214022
Product Name: Accu-Chek Softclix Blood Lancing System
Manufacturer: Roche Diabetes Care, Inc.

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

The proposed device, RightLance Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm.
The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.
This system is for use only on a single patient in a home setting.
This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.
The RightLance Blood Lancing System is made up of Lancing Device and Disposable Lancet.

The Model of Lancing Device: RC-AD-III; RC-AD-IIIT; RC-AD-VIU; RC-AD-VIX; RC-AD-VIXT; RC-AD-VII; RC-AD-XI; RC-AD-XII; RC-AD-XIV; Sinodraw; RC-LD-16; RC-LD-17; RC-LD-18; RC-LD-19

The Model of Disposable Lancet: I
Size: 21G, 23G, 25G, 26G, 27G, 28G, 30G, 31G, 32G, 33G

6. Indication for Use Statement [21 CFR 807.92(a)(5)]
The RightLance Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm.
The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.
This system is for use only on a single patient in a home setting.
This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting

7. Indication for Use Comparison [21 CFR 807.92(a)(5)]
The indications for use of the RightLance Blood Lancing System are the same as the predicate device, the Accu-Chek Softclix Blood Lancing System.

	Proposed Device K222034	Predicate Device K214022
Indications for use	The RightLance Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. This system is for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting	The Accu-Chek Softclix Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. This system is for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting

8. Technological Comparison [21 CFR 807.92(a)(6)]
The RightLance Blood Lancing System and predicate device share the same e technological characteristics including their design, mechanical mechanism, principle of operation, energy source

and usage, features, form, fit, and function.

	Proposed Device K222034	Predicate Device K214022
Device description	The Lancing Device uses compatible Disposable Lancet to obtain a drop of blood from a fingertip or alternative sites	The Accu-Chek Softclix Lancing Device uses compatible Accu-Chek Softclix Lancets to obtain a drop of blood from a fingertip or alternative sites using the Accu-Chek Softclix Alternative Site Testing (AST) Cap.
Number of Uses	Base (lancing device): multiple use Lancet: single use	Base (lancing device): multiple use Lancet: single use
Lancet Sterility	Yes, gamma irradiation	Yes, gamma irradiation
Needle	0.80mm (21G); beveled cut with 3 facets 0.60mm (23G); beveled cut with 3 facets 0.50mm (25G); beveled cut with 3 facets 0.45mm (26G); beveled cut with 3 facets 0.40mm (27G); beveled cut with 3 facets 0.37mm (28G); beveled cut with 3 facets 0.32mm (30G); beveled cut with 3 facets 0.26mm (31G); beveled cut with 3 facets 0.23mm (32G); beveled cut with 3 facets 0.20mm (33G); beveled cut with 3 facets	0.4mm (28G); beveled cut with 3 facets
Depth adjustment	RC-AD-III: 6 levels by adjusting cap(0.3mm-1.5mm) RC-AD-IIIT: 6 levels by adjusting cap(0.3mm-1.5mm) RC-AD-VIU: 6 levels by adjusting cap(0.7mm-2.2mm) RC-AD-VIX: 6 levels by adjusting cap(0.3mm-1.5mm)	11 levels by twisting cap(0.8mm-2.3mm)

	RC-AD-VIXT: 6 levels by adjusting cap(0.3mm-1.5mm) RC-AD-VII: 6 levels by adjusting cap(0.7mm-2.2mm) RC-AD-XI: 11 levels by adjusting cap(0.3mm-1.6mm) RC-AD-XII: 9 levels by adjusting cap(0.4mm-1.8mm) RC-AD-XIV: 9 levels by adjusting cap(0.4mm-1.8mm) Sinodraw: 10 levels by adjusting cap(0.4mm-1.6mm) RC-LD-16: 10 levels by adjusting cap(0.1mm-1.5mm) RC-LD-17: 5 levels by adjusting cap(0.1mm-1.5mm) RC-LD-18: 10 levels by adjusting cap(0.1mm-1.5mm) RC-LD-19: 10 levels by adjusting cap(0.1mm-1.5mm)	
Mechanical loading	Spring-driven	Spring-driven
Load and firing	● Load by pressing priming button when lancet is inserted, ● Fire by pressing the release button.	● Load by pressing priming button when lancet is inserted, ● Fire by pressing the release button.
Anatomical sites	● Fingertip ● Ball of the hand (palm) ● Upper arm ● Lower arm (forearm)	● Fingertip ● Ball of the hand (palm) ● Upper arm ● Lower arm (forearm)
Sharps injury prevention	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.

9. Non-Clinical Testing Summary [21 CFR 807.92(b)]

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.
The test results demonstrated that the proposed device complies with its design specification.
The bench testing performed shown as following:

ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-4:2017, Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
ISO 11137-2, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose – Method VD max.
USP34<151>, Rabbit Pyrogen Test
Performance Testing - Basic Size
Performance Testing – Puncture Depth
Performance Testing – Lancing Device Cap Removal
Performance Testing – Lancing Device Firing Force
Performance Testing – Drop
Performance Testing – Drawing Force
Performance Testing – The tightness of lancing device
Shelf Life (aging) Validation

10. Clinical Testing [21 CFR 807.92(b)]
Clinical Testing is not applicable;

11. Conclusions [21 CFR 807.92(b)]
The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.