November 30, 2022

Shandong Lianfa Medical Plastic Products Co. Ltd.
% Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K222472
Trade/Device Name: Lancing System, Sterile Lancet for Single Use, Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: October 12, 2022
Received: October 14, 2022

Dear Charles Shen:

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,

Jessica Carr -S

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)*
K222472

Device Name
Lancing System, Sterile Lancet for Single Use, Lancing Device

Indications for Use *(Describe)*
"Lancing System" consists of "Sterile Lancet for Single Use" and "Lancing Device"

The 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 reusable lancing device is to be used with sterile, single-use lancets, and is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.

The lancing device is for use only on a single patient in a home setting. This lancing device is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

"Sterile Lancet for Single Use" is a single use device indicated for capillary blood sampling. It can be used in conjunction with "Lancing Device" in home settings, or be used standalone in both home and hospital settings.

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:

This summary of 510k safety and effectiveness informationis being submitted
In accordance with the requirements of 21CFR 807.92

1 Submitter & Foreign Manufacture Identification

Shandong Lianfa Medical Plastic Products Co. Ltd.
No. 1 Shuangshan Sanjian Road
Zhangqiu, Jinan, Shandong Province, China, Zipcode 250200
Tel: (086) 531-61328777
Submitter's FDA Registration Number：3003723176

2 Contact Person

Dr. Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

3 Date of Summary: November 22, 2022

4 Device Name:

Trade Name:	Lancing System, Sterile Lancet for Single Use, Lancing Device
Common Name:	Lancing Device, Blood Lancet
Classification Name:	Multiple Use Blood Lancet For Single Patient Use Only/ Single Use Only Blood Lancet without An Integral Sharps Injury Prevention Feature
Device Classification:	Class 2
Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4850
Product Code:	QRL
Subsequent Product Code:	QRK

5 Predicate Device Information:

K214022, "Accu-Chek Softclix Blood Lancing System", manufactured by "Roche Diabetes Care, Inc."

6 Device Description:

"Lancing System" consists of "Sterile Lancet for Single Use" and "Lancing Device"

"Sterile Lancet for Single Use" is a single use, sterile, medical devices designed to be used in collecting the blood sample. The products are intended to be used by professionals in hospital settings or patients at home.

"Sterile Lancet for Single Use" is a disposable blood lancet intended for a single use that is comprised of a cap, a single use blade attached to a solid, non-reusable base, and it is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The needle is protected with a cap before use. The steel needle is made of stainless steel SUS304. The needle cap and needle base are made of polyethylene plastic, and are injection molded. The Sterile Lancet for Single Use is sterilized by gamma irradiation.

"Sterile Lancet for Single Use" can be used alone in either home or healthcare settings, or be used together with "Lancing Device" in home settings.

Based on different design and shape, there are three different types of "Sterile Lancet for Single Use", and also can accommodate different needle gauges.

"Lancing Device" is a multiple use, sterile, medical devices designed to be used in collecting the blood sample. The products can be used by patients and lay persons. They are not intended for healthcare workers because the device can not be used among different patients.

Lancing Device is a multiple use capillary blood lancet intended for use on a single patient. Before each use, a single use lancet is attached to the reusable case, and when launched, is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

After use, the single use blade ("Sterile Lancet for Single Use") is disposed of, and the lancing device is cleaned and disinfected, ready for the next use.

The lancing device has five adjustable gears (marked 1 to 5) that allow for different puncture depth.

Lancing Device is made of a needle base, spring, a launching part, return spring, launch button, a casing, and a cap. The needle is made of SUS304 stainless steel, the spring material is carbon steel, and the other parts are made of plastic components.

7 Indications for Use:

"Lancing System" consists of "Sterile Lancet for Single Use" and "Lancing Device"

The 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 reusable lancing device is to be used with sterile, single-use lancets, and is to be cleaned and disinfected between each use, and then the lancets are to be disposed of.

The lancing device is for use only on a single patient in a home setting. This lancing device is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

"Sterile Lancet for Single Use" is a single use device indicated for capillary blood sampling. It can be used in conjunction with "Lancing Device" in home settings, or be used standalone in both home and hospital settings.

8 Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between the subject Lancing System and the predicate device K214022, Accu-Chek Softclix Blood Lancing System.

Table 1: Comparison of Intended Use, Design, Material, and Processing: Lancing System

Description	Subject Device	Predicate Device (K214022)	SE Determination
Indication for Use	"Lancing System" consists of "Sterile Lancet for Single Use" and "Lancing Device" The 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 reusable lancing device is to be used with sterile, single-use lancets, and is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. The lancing device is for use only on a	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.	Similar

	single patient in a home setting. This lancing device is not suitable for use by healthcare professionals with multiple patients in a healthcare setting. "Sterile Lancet for Single Use" is a single use device indicated for capillary blood sampling. It can be used in conjunction with "Lancing Device" in home settings, or be used standalone in both home and hospital settings.		
Regulation Number	21 CFR § 878.4850	21 CFR § 878.4850	SE
Product Code	QRL/QRK	QRL/QRK	SE
Regulation Name:	Lancing Device: Multiple Use Blood Lancet For Single Patient Use Only Single Use Lancet: Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	Lancing Device: Multiple Use Blood Lancet For Single Patient Use Only Single Use Lancet: Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	
Basic Design	Lancing Device: Housing, protective cap, spring, button Single Use Lancet: Stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	Lancing Device: Housing, protective cap, spring, button Disposable needle: Stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	SE
Patient Contact Materials	Stainless steel, and plastics	Stainless steel and plastics	
Use Environment	Lancing Device: This system is for use only on a single patient in a home setting. The Lancing Device is not suitable for use by healthcare professionals Lancet: This system is for use only on a single patient in a professional or home setting.	Lancing Device: This system is for use only on a single patient in a home setting. The Lancing Device is not suitable for use by healthcare professionals Lancet: This system is for use only on a single patient in a professional or home setting.	SE
Depth Adjustment	5 levels	11 level	Similar
Single/Multiple Use	Lancing Device: multiple use Sterile Lancet for Single Use: single	Lancing Device: multiple use Lancet: single use	SE

	use		
Mechanism	Spring firing Manual disposal of lancet	Spring firing Manual disposal of needle	SE
Sharp Prevention Features	Yes	Yes	SE
Shelf Life	5 years	5 years	SE
Sterile	Lancing Device: Not sterilized Sterile Lancet for Single Use: SAL 10^{-6}	Lancing Device: Not sterilized Sterile Lancet for Single Use: SAL 10^{-6}	SE
Prescription/OTC	Prescription/OTC	OTC	SE
Intended Patient Populations	All ages	All ages	SE

The subject Lancing System is essentially identical to the predicate device in terms of indications for use, design, material, and processing. The minor differences do not affect the safety and performance of the device

9 Summary of Device Non-Clinical Performance Testing:

Bench testing was performed per internal procedures to ensure that the "Lancing System" met its specifications. The following tests were performed:

- Physical properties (appearance, dimension)
- Chemical properties (pH, metal, sterility, corrosion resistance)
- Mechanical properties (launch performance, puncture force, puncture depth, drop test, twist force, detach force, structure firmness)
- Injury preventing features
- Bacterial endotoxin
- Packaging integrity
- Stability evaluation
- Use life study
- Sterilization validation

All tests were verified to meet acceptance criteria.

10 Biocompatibility Testing

Biocompatibility testing was performed to verify the equivalence of the materials that are used. The following Biocompatibility properties are tested for the subject device

Description	Test Standard
Cytotoxicity	ISO 10993-5
Irritation Oral Mucosa Irritation	ISO 10993-10
Sensitization	ISO 10993-10
Acute Toxicity	ISO 10993-11
Pyrogenicity	ISO 10993-3

The results show that "Lancet System" does not cause biocompatibility concerns.

11 Clinical Testing

No clinical study is included in this submission

12. Conclusion

The proposed device of "Lancing System" which consists of "Sterile Lancet for Single Use" and "Lancing Device" has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is as safe and effective as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.