10/3/2022

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

Re: K222376
Trade/Device Name: Lianfa Safety Lancet (Five Models: NPA, PA, PA2, TPA, and APA)

Regulation Number: 21 CFR 878.4800
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 5, 2022
Received: August 5, 2022

Dear Dr. 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,

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

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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)*
K222376

Device Name
Lianfa Safety Lancet

Indications for Use *(Describe)*
Lianfa Safety Lancet (Five Models: NPA, PA, PA2, TPA, and APA) is a single use device indicated for capillary blood sampling.

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) Number: K222376

510(k) Summary:

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

I 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

Contact Person

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

Date of Summary: October 3, 2022

II Device Name:

Trade Name:	Lianfa Safety Lancet (Five Models: NPA, PA, PA2, TPA, and APA)
Common Name:	Blood Lancet
Classification Name:	Single Use Only Blood Lancet with An Integral Sharps Injury Prevention Feature
Device Classification:	Class 2
Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4850
Product Code:	FMK

III Predicate Device Information:

(1) K220370, "Safety Lancet (8 Models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI)", manufactured by "Tianjin Huahong Technology Co., Ltd."

IV Device Description:

Lianfa Safety Lancet 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 and home users. They are intended for over the counter use.

Lianfa Safety Lancet is a disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

The safety lancet is made up of a needle core, spring, a launching part, and a casing. The steel needle is made of SUS304 stainless steel, the spring material is carbon steel, and the other parts are made of plastic components. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.

Based on the shape and design of the device, there are five different models: PA, PA2, APA, NPA, and TPA. Each model is offered with various gauges of needle.

V Indications for Use:

Lianfa Safety Lancet (Five Models: NPA, PA, PA2, TPA, and APA) is a single use device indicated for capillary blood sampling.

VI Comparison of Technological Characteristics with the Predicate Device

The comparison and discussion between the subject device and the predicate device are listed in below Table 1:

Table 1: General Comparison of Safety Lancet

Description	Subject Device	Predicate Device (K220370)
Product Name	Lianfa Safety Lancet	Safety Lancet
Indication for Use	The safety lancet is a single use device indicated for capillary blood sampling.	The safety lancet is intended for capillary blood sampling.
Regulation Number	21 CFR § 878.4850	21 CFR § 878.4850
Product Code	FMK	FMK
Basic Design	Needle, housing, protective cap, spring, button	Needle, housing, protective cap, spring, button

Materials	Stainless steel, carbon steel, plastics	Stainless steel, carbon steel, plastics
Safety Features	Deactivated after first use	Deactivated after first use
Dimension	Various	Various
Compatible Gauges	17G, 18G, 21G, 23G, 25G, 26G, 28G, 30G (for all five models)	This information is not publicly available for predicate device
Range of Puncture Depth/Needle Length	Model NPA: 1.5 mm to 2.2 mm Model PA: 1.5 mm to 2.2 mm Model PA2: 1.5 mm to 2.2 mm Model APA: 1.0 mm to 2.2 mm Model TPA: 1.6 mm to 1.8 mm	This information is not publicly available for predicate device
Single Use	Yes	Yes
Shelf Life	5 years	5 years
Sterile	SAL 10^{-6}	SAL 10^{-6}
Prescription/OTC	OTC	OTC
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801

Conclusion: Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate device.

VII Non-Clinical Testing

The bench testing performed verifies that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device in terms of critical performance characteristics. These tests are as follow.

Characteristics	Specifications	Results
Appearance	The surface of the device and needle shall be clean, free of burrs, scratches, rusts, and any extraneous materials Needle should be clean, straight and without residual debris.	Meet requirement
Dimension	Product dimensions shall be consistent to the drawings	Meet requirement
Puncture Depth	Use calipers to measure and meet	Meet requirement
Corrosion	The steel needle shall be free of signs of corrosion	Meet requirement
Puncture Force	The steel needle puncture force shall be less than or equal to 2.0 N	Meet requirement
Connection Firmness between Needle and	The steel needle and the handle shall withstand 10N axial static tension for 1min	Meet requirement

Handle	and the handle.	
Sterility	The safety needle should be sterile.	Meet requirement
pH	The pH value between test solution and control solution shall not be greater than 1.	Meet requirement
Extractable Metal	Not more than 10 μg/device	Meet requirement
Launch Performance	Launch performance should be good, launch button can be pressed smoothly, no jam.	Meet requirement
Safety Features	The force to trigger a needle launch should be between 4 and 10 N. Deactivation: the product cannot be launched after the first launch.	Meet requirement

Biocompatibility Testing:

The biocompatibility evaluations were conducted in accordance with the 2020 FDA Guidance document Use of International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process" . The tests include the following tests:

Item	Test method	Test results
In Vitro Cytotoxicity	ISO 10993-5: 2009	No Cytotoxicity
Skin Sensitization	ISO 10993-10: 2010	No Skin sensitization
Intracutaneous reactivity	ISO 10993-10: 2010	No irritation
Acute Systemic Toxicity	ISO 10993-11: 2017	No Acute Systemic Toxicity
Pyrogenicity	ISO 10993-11: 2017	No thermogenic reaction

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

The proposed 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 predicate device. Accordingly, the proposed device is substantially equivalent to the predicate device.