September 21, 2022

Shanghai Carelife International Trading Co. Ltd.
% Evan Hu
Marketing & Technical Manager
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, Shanghai 201114
China

Re: K221383
Trade/Device Name: MedtFine Blood Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK
Dated: August 18, 2022
Received: August 23, 2022

Dear Evan Hu:

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,

Colin Chen
Acting 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)*
K221383

Device Name
MedtFine Blood Lancet

Indications for Use *(Describe)*
MedtFine Blood Lancet is intended for use together with a lancing device for puncture of skin to obtain a drop of capillary blood from fingertip or from alternative sites.

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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K221383 510(K) SUMMARY

1. Preparation date: 9/16/2022

2. Submitter

   Manufacturer: Shanghai Carelife International Trading Co. Ltd.
   Address: 1707 Yinqiao Bldg.,58 Jinxin Rd.201206 Shanghai, PEOPLE'S REPUBLIC OF CHINA
   Contact person: Zhang Xiaoying, Quality Manager, Tel: +862158542656, zxy@shanghaicarelife.com
   Submission correspondent: Evan Hu, 86-18616124827, Evan.hu@mind-link.net

3. Device

   Trading name: MedtFine Blood Lancet
   Common name: Sterile Blood Lancet
   Classification Name: Single Use Only Blood Lancet Without an Integral Sharps Injury Prevention Feature
   Classification: Class II
   Product code: QRK

4. Predicate device

   Primary predicate device: Promisemed Blood Lancet - K192666
   Reference device: Accu-Chek Softclix Blood Lancing System - K214022

5. Device description

   MedtFine Blood Lancet is a small medical device used for capillary blood sampling. It is similar to a small scalpel with a double-edged needle used to make punctures, such as a fingerstick, to obtain small blood specimens.
   The device consists of a needle sheath, a hub, and a needle and provided sterility that is sterilized by gamma radiation. The device has three types listed in table 1 with recognized color.
   The device is an over-the-counter instrument equipped with a lancing device that patients mostly use during blood monitoring. However, in this case, it doesn't contain a lancing device, only the lancet. The proposed device is a universal device that can be fitted with most common marked lancing devices.

Table 1. Device models

Gauge Size	Designated metric size	Color
28G	0.36	Green-Blue
30G	0.30	Grey-Blue
33G	0.20	Transparent

6. Indications for use/Intended use

MedtFine Blood Lancet is intended for use together with a lancing device for puncture of skin to obtain a drop of capillary blood from fingertip or from alternative sites.

7. Comparison of technological characters between proposed and predicate devices

Table 2. Characters comparison

Characters	Proposed device (K221383- MedtFine Blood Lancet)	Primary predicate device (K192666-Promisemed Blood Lancet)	Reference device (K214022- Accu-Chek Softclix Blood Lancing System)	Remark
Product code	QRK	FMK	QRL, QRK	#1
Regulation No.	21 CFR 878.4850	21 CFR 878.4800	21 CFR 878.4850	#2
Classification	Class II	Class I	Class II	#3
Intended use	MedtFine Blood Lancet is intended for use together with a lancing device for puncture of skin to obtain a drop of capillary blood from fingertip or from alternative sites.	It is intended for capillary blood sampling.	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.	#4
Indications for use			Accu-Chek Softclix Lancets: 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.	#5

Type of use	over-the-counter	over-the-counter	over-the-counter	Same
Configuration and materials	Needle sheath: PE Hub: PP Needle: SUS 304	Cap: PE Body: PE Needle: SUS	Cap Body Needle	#6
Needle Gauge	28G, 30G, 33G	21G, 26G, 28G, 30G	28G	#7
Sterility	Sterilized by gamma radiation SAL = 10^{-6}	Sterilized by gamma radiation SAL = 10^{-6}	Sterilized by gamma radiation SAL = 10^{-6}	Same
Single-use	Single use on one patient, no more than one use	Single use on one patient, no more than one use	Single use on one patient, no more than one use	Same
Sharp injury protection	No sharp injury protection function	No sharp injury protection function	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	#8
Intended population	Child older than 2 years Adolescent Adult	Adult	Not known	#9
Visual inspection	(a) Smooth, clean, free from contamination (b) No color fading (c) Sharp edge, free from burrs, hook, and blunt. (d) Straight, no slanting Meet visual checking requirements of ISO 9626, ISO 7864, and internal requirements	Meet visual checking requirements of ISO 9626 and ISO 7864	Not known	#10
Needle dimension-	33G: 3.47 mm 30G: 3.52 mm	21G: 3mm 26G: 3mm 28G: 3mm	Not known	#11

exposed needle length	28G: 3.25 mm	30G: 3mm		
Needle dimension-OD	33G: 0.20 mm 30G: 0.32 mm 28G: 0.36 mm Meet needle outer dimension requirements of ISO 9626	Meet needle outer dimension requirements of ISO 9626	Not known	Same
Chemical Characters	Limits for acidity or alkalinity 33G: 0.31 30G: 0.29 28G: 0.34 Meet requirements of ISO 7864	Meet requirements of ISO 7864	Not known	Same
Needle bond force	33G: 12.15 N 30G: 15.87 N 28G: 15.39 N Meet requirements of ISO 7864	Meet requirements of ISO 7864	Not known	Same
Resistance to corrosion	No corrosion in NaCl solution for 7 hours Meet corrosion resistance requirements of ISO 9626	Meet corrosion resistance requirements of ISO 9626	Not known	Same
Lancing device compatibility	As a universal device, it is compatible with various commercially marketed lancing devices verified in usability testing.	It claims to be compatible with lancing devices.	It claims to be compatible with the Accu-Chek Softclix Blood Lancing System	Same
Penetrate force/puncture force	33G: 0.388 N 30G: 0.543 N 28G: 0.545 N Meet requirements of ISO 7864	30G: 0.656 N 28G: 0.751 N Meet requirements of ISO 7864	Not Known	#12
Biocompatibility	No hemolysis No cytotoxicity No irritation and no skin sensitization No acute systemic toxicity No pyrogens	No cytotoxicity No irritation and no skin sensitization	Not Known	#13

#1, #2 and #3:

Single-use only blood lancet without an integral sharps injury prevention feature was once a Class I device exempted from 510(k) registration. However, the regulation was last amended, and the device is reclassified to Class II, effective on 12/03/2021. The device is given the

product code QRK under regulation 21 CFR part878.4850. So, the differences are administrative differences, which cannot affect the device's safety and effectiveness.
The reference device is a combination device that consists of a lancet and a lancing device. In this case, only the lancet is used to be compared. So, there is no difference in product code, regulation number, and classification.
In conclusion, the proposed device, primary predicate, and reference devices are substantially equivalent.

#4 and #5
There is no difference of intended use and indication for use between the proposed device and the primary predicate device. They are both intended to equip with a lancing device and then puncture the skin to obtain capillary blood.
However, the reference device is a combination system, and only the lancet is compared. For this view, there is also no difference.
In conclusion, the proposed device, primary predicate, and reference devices are substantially equivalent.

#6:
The configurations are different. The proposed device has a removable needle sheath (or called a cap). The user could directly remove the needle sheath and load it to a lancing device. However, the primary and reference devices have an integrity structure, which means the cap, body, and needle are over-molded together from an injection machine. The user should twist the cap to expose the needle and the load to a lancing device. The differences are rising from the different manufacturing processes. So, the process validation and device performance testing are run to verify the device's effectiveness.
The materials used are different. Due to the integrity structure, the primary predicate and reference devices only use PE to make the cap and body. However, the proposed device uses PE to make the sheath (cap) and PP to make the hub (cap) due to two separated manufacturing processes and late assembly. So, biocompatibility testing is run to verify the device's safety.
The proposed device uses SUS 304 to make a needle; however, the predicate device does not reveal the exact stainless-steel grade. The difference between different SUS grades is their performance. So, performance testing is conducted to verify the device's effectiveness.
In conclusion, the proposed device, primary predicate, and reference devices are substantially equivalent.

#7:
The proposed device has three types of gauge, more than the primary and reference device. The primary predicate device has four types, according to their official website, and the reference device only has one type. So, all proposed device types' performance testing is run to verify the device's effectiveness.

In conclusion, the proposed device, primary predicate, and reference devices are substantially equivalent.

#8:
Unlike the reference device, the proposed and predicate devices do not claim sharp injury protection features, meaning they don't contain the sharp injury prevention structure. It cannot affect safety and effectiveness.

#9: The intended population of the proposed device is wider than the primary predicate device. So, the manufacturer conducts population evaluation testing, and the results support the intended population, demonstrating substantial equivalence.

#10: The proposed device uses an additional internal requirement to conduct the device's visual checking to confirm no deficiencies in visual appearance. The internal requirements are derived from the visual checking sections of ISO 9626 and ISO 78664. The visual checking results meet all requirements, so there is no significant difference compared with the predicate device, demonstrating substantial equivalence.

#11: The needle length of the proposed device is slightly longer than the predicate device. Testings of performance and usability show no impact of a slightly longer needle on device properties because the exposed needle length is tuned by the lancing device, not the lancet itself, demonstrating the substantial equivalence.

#12: The proposed device's penetrate force (puncture force) is lower than the primary predicate device, meaning that the proposed device lancet is easier to puncture into the patient's skin, resulting in a less painful feeling for patients. Results show that the proposed device is comparable to the predicate device in the penetrate force, demonstrating substantial equivalence.

#13: The proposed device conducts six items of biocompatibility testing, but the predicate device only conducts three items. Results show that the proposed device is as safe as the proposed device, demonstrating substantial equivalence.

8. Non-clinical testing results

The non-clinical tests of this proposed device are tested in conformance with the following standards.

(1) Physical performance testing
(a) ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Device.
(b) ISO 7864-2016 Sterile hypodermic needles for single use - requirements and test methods

(c) ISO 11608-1:2014 Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems
(d) ISO 11608-2 Needle-based injection system s for medical use — Requirements and test methods — Part 2: Double-ended pen needles

(2) Sterility
(a) ISO 11737-1:2018, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
(b) ISO 11737-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
(c) ISO 11137-1:2006, Radiation sterilization of medical devices part 1: Requirements for the development, validation and routine control of the sterilization process of medical devices.
(d) ISO 11137-2:2013, Radiation sterilization of medical devices part 2: Determination of sterilization dose.
(e) ISO11137-3： 2006 Radiation sterilization of medical devices part 3: Dosage guidelines.
(f) ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
(g) ISO 11607-2:2019, Packaging for terminally sterilized medical devices--Part 2: Validation requirements for forming, sealing and assembly processes
(h) ASTM F1980: Standard for Accelerated Aging of Sterile Barrier Systems and Medical Devices
(i) ASTM F1929: 2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
(j) ASTM D4169-16 Standard Practice For Performance Testing Of Shipping Containers And Systems
(k) USP <71> Sterility Test

(3) Biocompatibility testing
(a) ISO10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
(b) ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood.
(c) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
(d) ISO 10993-10:2010, Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization.
(e) ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity.
(f) USP <85> Bacterial Endotoxins Test
(g) USP <788>Particulate matter in injection

(h) USP <161>Medical Devices-Bacterial endotoxin and pyrogen tests

9. Clinical testing
   No clinical testing is available for this device.

10. Conclusion
    The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.