January 25, 2023

Sarstedt AG & CO KG
% Susan Smith
Quality Manager
Sarstedt, Inc.
1025 St. James Church Road
Newton, North Carolina 28658

Re: K222801
Trade/Device Name: Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: October 20, 2022
Received: October 24, 2022

Dear Susan Smith:

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 K. Chen -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)*
K222801

Device Name
Safety-Lancet

Indications for Use *(Describe)*
Safety-Lancets with safety feature are used for single use 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.

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(5) 510(k) Summary Prepared January 10, 2023

Submission # K222801

Submission Sponsor

SARSTEDT AG & CO KG

Sarstedtstrasse 1 Nuembrecht North Rhine – Westphalia 51588 Germany

Contact: Jochen Hoffmann Phone: 49 2293 305 4100

Submission Correspondent

SARSTEDT, Inc.

1025 St. James Church Road, Newton, NC 28658 USA

Contact: Susan Smith Phone: 828-468-6655

Device identification

Trade Name:	Safety Lancet®
Product Nomenclature:	Single use blood lancet with an integral sharps injury with prevention feature
	Class II
	79 FMK
	21 CFR 878.4850

Legally Marketed Predicate Device

Trade Name:	Safety Lancet®
Product Nomenclature:	Blood lancet
	Class I
	79 FMK
	21 CFR 878.4800

Device Description

The Safety Lancet consists of the following components: colorless plastic body, needle holder with needle or blade shaped lancing device, protective cap, carrier device, two springs, and the release button. The release button, the needle holder, and the protective cap are colored according to the variant available.

The lancets are offered with different needle or blade shaped lancing devices, different sharpening and penetration depths, and accordingly in different colors. The lancets contain a safety feature. After puncture the needle retracts automatically into the housing to prevent sharps injuries.

Item number	Description	Specification	Color
85.1015	Safety-Lancet Mini 28G	Penetration depth: 1,6 mm; Cross-section: 0,09858 mm^2	
85.1016	Safety-Lancet Normal 21G	Penetration depth: 1,8 mm; Cross-section: 0,4035 mm^2	
85.1017	Safety-Lancet Extra 18G	Penetration depth: 1,8 mm; Cross-section: 0,4680 mm^2	
85.1018	Safety-Lancet Super Blade 1,5 mm	Penetration depth: 1,6 mm; Cross-section: 0,4639 mm^2	
85.1019	Safety-Lancet Neonatal Blade 1,5 mm	Penetration depth: 1,2 mm; Cross-section: 0,2574 mm^2	

Intended Use/Indications for Use

Safety-Lancets with safety feature are used for single use capillary blood sampling.

Specification

The products are intended for human use in a professional environment by qualified medical personnel.

Technological characteristics comparison

Comparison item	Safety Lancet	Safety Lancet
Manufacturer	SARSTEDT	SARSTEDT
510(k)	submitted	Exempt Class I
Classification	FMK	FMK
Intended Use	Intended for single use capillary blood sampling	Intended for single use capillary blood sampling
User	qualified medical personnel in hospitals, clinics and reference laboratories	qualified medical personnel in hospitals, clinics and reference laboratories
Materials contacting patient	Housing – PP Needle/blade cover - PS Needle/blade – Stainless steel Needle/blade lubricant - silicone Push button – PP	Housing – PP Needle/blade cover - PS Needle/blade – Stainless steel Needle/blade lubricant - silicone Push button – PP
Components	Housing, Drive spring, Return spring, Lever, Needle/blade, Needle/blade cover, Push button	Housing, Drive spring, Return spring, Lever, Needle/blade, Needle/blade cover, Push button
Device characteristics	Specification / Penetration 28 G / 1,6 mm 21 G / 1,8 mm 18 G / 1,8 mm Blade 1,5 mm / 1,6 mm Blade 1,5 mm / 1,2 mm	Specification / Penetration 28 G / 1,6 mm 21 G / 1,8 mm 18 G / 1,8 mm Blade 1,5 mm / 1,6 mm Blade 1,5 mm / 1,2 mm
Safety protection features	Yes, after puncture the needle retracts automatically into the housing to prevent sharps injuries.	Yes, after puncture the needle retracts automatically into the housing to prevent sharps injuries.
Reuse durability	Single use	Single use
Shelf Life	5 years	5 years

Sterilization method and SAL	Sterilize by radiation SAL = 10^{-6}	Sterilize by radiation SAL = 10^{-6}
Labeling	According to 21 CFR 801, 809, 830, 878.4850	According to 21 CFR 801, a809, 830 878.4800

Summary of non-clinical testing

Bench tests were conducted to verify that the proposed device met all design specifications and to prove that the device was substantially equivalent to the predicate device.

The design specification tests included:

- Aesthetics and correct assembly
- Inspection for self-activation
- Activation according to instructions for use
- Needle retraction after activation

The testing also included sterilization validation, packaging validation, shelf-life validation, and biocompatibility testing.

Conclusion

The Safety Lancet pre November 22, 2021 and the Safety Lancet described in this submission are physically and functionally the same. The non-clinical testing has shown that the Safety Lancet is as safe, as effective and performs as well as the legally marketed predicate device. The products will differ on the required labelling described in 21 CFR 878.4850.