



July 1, 2025

HTL-Strefa S.A.
Justyna Zemigala
Regulatory Affairs Manager
Adamówek 7
Ozorków, 95-035
Poland

Re: K250016

Trade/Device Name: droplet® personal lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK
Dated: January 3, 2025
Received: January 3, 2025

Dear Justyna Zemigala:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Digitally signed by
Jang -S James H. Jang -S
Date: 2025.07.01
08:16:15 -04'00'

James Jang
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

Indications for Use

510(k) Number (if known)
K250016

Device Name
droplet® personal lancets

Indications for Use (Describe)

droplet® personal lancets are sterile, single-use medical devices intended to be used with a lancing device by lay users 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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Traditional 510(k) for droplet® personal lancets
Submitted Under 21 CFR § 807.87

510(k) Summary

As required by the Safe Medical Devices Act of 1990 and in accordance with 21 CFR §807.92(a).

Summary

[807.92 (a)(1,2)]

Date prepared: January 3rd, 2025

Submitted by: HTL-Strefa S.A.
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Trade Name: droplet® personal lancets

Common Name: blood lancets

Regulation Number: 21 CFR § 878.4850

Product Code: QRK

Device Classification: Class II

Review Panel: General and Plastic Surgery

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Predicate Device:**[807.92 (a)(3)]****The legally marketed device to which substantial equivalence is claimed is:**

Manufacturer Name	Trade Name	510(k) Number
SteriLance Medical (Suzhou) Inc.	Disposable Blood Lancet	K221507

Description of Device:**[807.92 (a)(4)]**

droplet® personal lancets are sterile, single-use medical devices intended to be used with a lancing device by lay users for capillary blood sampling. The patient target population of this device is the population from children to adults.

droplet® personal lancet is made of steel needle placed inside the plastic body lancet with plastic protective cap.

The lancet remains sterile until the cap is removed. There are two versions of droplet® personal lancets which differ in the needle diameter: 28G and 30G. These two versions differ in lancet body color. The version 28G is available in pink and blue colors, and version 30G is available in violet version.

Principles of Operation:

The droplet® personal lancets cooperate with lancing device. The protective cap of the lancet is twisted and removed to expose the needle. The lancing device loaded by lancet is placed against the puncture site and activated. Pressure is applied near to the puncture site (if necessary, intermittently) to obtain the required blood sample. The lancet is disposed in an appropriate biohazard container after use. Lancing device holds a lancet firmly, and when triggered, moves the lancet linearly ahead to prick the skin in a controlled manner. Lancing device can be adjusted to alter the depth that the lancet goes into the skin. The purpose is to obtain a small amount of capillary blood for testing.

Indications for Use:**[807.92 (a)(5)]**

droplet® personal lancets are sterile, single-use medical devices intended to be used with a lancing device by lay users for capillary blood sampling.

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Technological Characteristics:

[807.92 (a)(6)]

A comparison characteristics of droplet® personal lancets and predicate device is shown in the table below:

Feature	Subject Device	Predicate Device	Conclusion
<i>510(k) Number</i>	pending	K221507	510(k) number for Subject Device is pending
<i>Classification</i>	Class II	Class II	The same
<i>Regulation number</i>	21 CFR § 878.4850	21 CFR § 878.4850	The same
<i>Product Code</i>	QRK	QRK	The same
<i>Type of use</i>	Over-The-Counter Use (OTC)	Over-The-Counter Use (OTC)	The same
<i>Indications for Use</i>	droplet® personal lancets are sterile, single-use medical devices intended to be used with a lancing device by lay users for capillary blood sampling	Disposable Blood Lancet is used for capillary blood collection	The same
<i>Patient target population</i>	From children to adults	Adult and pediatric	The same
<i>Reuse durability</i>	Single use	Single use	The same
<i>Sterilization method and SAL</i>	Sterilized by irradiation SAL=10 ⁻⁶	Sterilized by irradiation SAL=10 ⁻⁶	The same
<i>Shelf life</i>	5 years	5 years	The same
<i>Biocompatibility</i>	Conforms to ISO 10993-1	Conforms to ISO 10993-1	The same
<i>Components</i>	Needle, lancet body, protective cap	Needle, lancet body, protective cap	The same
<i>Needle diameter</i>	28G, 30G	21G, 23G, 26G, 28G, 30G, 32G, 33G	The same. Needle diameters 28G and 30G of the subject device are within the diameter range

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Feature	Subject Device	Predicate Device	Conclusion
			of the predicate device.
<i>Materials</i>	Needle: stainless steel; lancet body and protective cap: polyethylene	Needle: stainless steel, lancet body and protective cap: polyethylene	The same

Based upon the above comparisons to the predicate device, droplet® personal lancets do not raise any new issues of safety and effectiveness.

Non-Clinical Performance Data:

[807.92 (b)(1)]

The safety and effectiveness studies for droplet® personal lancets were performed to demonstrate compliance with the established requirements by manufacturer as per product specifications. These tests were conducted by quality control and included: color and aesthetics, presence of one raw needle in the lancet, orientation of raw needle in the lancet, point sharpness and lancet length without the needle protective cap (raw needle protrusion from the molding). All tests were passed and met the predefined acceptance criteria.

The cooperation of the droplet® personal lancets with lancing devices was tested. The aim of the tests was to evaluate the compatibility of droplet® personal lancets manufactured by HTL-Strefa S.A. with selected commercially available lancing devices from different manufacturers. The following test parameters were assessed: possibility to install the lancet in the lancing device and stability of the lancet in the lancing device; properly closing of the lancing device after inserting the lancet; possibility of the loading and activating the lancing device with inserted lancet; rotating the lancet in the lancing device when twisting off the protective cap; lancet needle protrusion from the lancing device; retraction of the lancet needle when activating the lancing device. The results of the above tests were used to establish the current list of lancing devices cooperating with droplet® personal lancets, as a part of the information provided with the product.

Additionally non-clinical performance data were obtained after carrying out biocompatibility, sterilization and transport tests.

During the transport tests, the devices were exposed to mechanical hazards to check whether the pre-determined packaging method is appropriate for their transporting to distribution centers, customers and secures the devices from damage. The aim of the test was to verify the integrity of the shipper, primary boxes and also correctness of the finished product subjected to transport exposure hazards. Tests imitate the extreme exposures that the product can be subjected during packaging, transport and storage activities. After performed tests, all product components are complete. The product is not being poured out of the transport. After transport exposures, the product meets the predefined requirements. The device was not damaged and did not lose its technological performance.

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Clinical Performance Data:

[807.92 (b)(2)]

Clinical data is not required.

Conclusion:

[807.92 (b)(3)]

The droplet® personal lancets are concluded to be substantially equivalent in the intended use, technology/principle of operation, materials and performance to the legally marketed predicate device cleared under K221507.