July 8, 2022

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

Re: K220643/S001
Trade/Device Name: DropSafe Acti-Lance Safety Lancets; droplet ACTI-LANCE Safety Lancets, DropSafe Medlance Plus Safety Lancets; droplet MEDLANCE PLUS Safety Lancets, DropSafe ergoLance Safety Lancets, DropSafe Prolance Safety Lancets, DropSafe Medisafe Solo Safety Lancets; DropSafe Haemolance Plus Safety Lancets
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class II
Product Code: FMK
Dated: June 7, 2022
Received: June 13, 2022

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 (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

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)*

Device Name
DropSafe Acti-Lance Safety Lancets; DropSafe ergoLance Safety Lancets; DropSafe Medlance Plus Safety Lancets; DropSafe Prolance Safety Lancets; DropSafe Haemolance Plus Safety Lancets; DropSafe Medisafe Solo Safety Lancets; droplet ACTI-LANCE Safety Lancets; droplet MEDLANCE PLUS Safety Lancets

Indications for Use *(Describe)*
Sterile, single use medical devices intended 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.

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HTL-STREFA S.A.
Traditional 510(k) for DropSafe Safety Lancets
and droplet Safety Lancets
Submitted Under 21 CFR 807.90(e).

5. 510(k) Summary

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

[807.92 (a)(1,2)]

Date Summary Prepared: 28 February, 2022

Submitted by:
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Trade Name:
DropSafe Acti-Lance Safety Lancets
DropSafe ergoLance Safety Lancets
DropSafe Medlance Plus Safety Lancets
DropSafe Prolance Safety Lancets
DropSafe Haemolance Plus Safety Lancets
DropSafe Medisafe Solo Safety Lancets
droplet ACTI-LANCE Safety Lancets
droplet MEDLANCE PLUS Safety Lancets

Models:
type 610 *(DropSafe Acti-Lance Safety Lancets; droplet ACTI-LANCE Safety Lancets)*
type 450 *(DropSafe ergoLance Safety Lancets)*
type 553-556 *(DropSafe Medlance Plus Safety Lancets; droplet MEDLANCE PLUS Safety Lancets)*
type 430 *(DropSafe Prolance Safety Lancets)*
type 420 *(DropSafe Haemolance Plus Safety Lancets)*
type 520 *(DropSafe Medisafe Solo Safety Lancets)*

HTL-STREFA S.A.
Traditional 510(k) for DropSafe Safety Lancets
and droplet Safety Lancets
Submitted Under 21 CFR 807.90(e).

Common name: Blood lancets

Regulation Number: 21 CFR § 878.4850

Product Code: FMK

Device Classification: II

Review Panel: 79 General and Plastic Surgery

Predicate Device
[807.92(a)(3)]

The legally marketed devices to which substantial equivalence is claimed are:

Manufacturer	Trade Name	510(k) Number
Promisemed Hangzhou Meditech Co., Ltd.	*VeriFine Safety Lancet*	K192666

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

Device description
DropSafe/droplet Safety Lancets and are manufactured by HTL-STREFA S.A. under different, individual brand names. The devices share the same intended purpose, risk class and manufacturing characteristics. *DropSafe/droplet Safety Lancets* are sterile, single use medical devices intended for capillary blood sampling. *DropSafe/droplet Safety Lancets* are OTC devices intended to be used by healthcare professionals and lay users. So far, these lancets were available on the US market as medical devices classified as class I.
The devices have similar design and are gamma sterilized. *DropSafe/droplet Safety Lancets* comprise needle or blade and are offered with different gages and lengths (different skin penetration depths after puncture).
DropSafe/droplet Safety Lancets are sterile until protective cap is removed. *DropSafe/droplet Safety Lancets* are push-button activated or activated by pressing the device against the puncture site (contact activation). Regardless of the activation mechanism, the devices are designed to minimize the risk form accidental needle/blade sticks with a used needle/blade by application sharps prevention feature. Following use, the needle/blade retracts into the housing which prevents reuse and accidental sticks.
The devices are packed in various quantities in boxes.

DropSafe/droplet Safety Lancets share the same technological design and principle of operation. The selected models comprise a needle or a blade. The only differences relate to the shape of the outer housing of the devices and the method of their activation.

DropSafe/droplet Safety Lancets comprise the following common elements:

- Injection molded housing,
- Complete needle/blade coated with a silicone as a lubricant (a steel needle/blade molded with plastic),
- Needle/blade cap,
- Injection molded pushbutton (in a case of push-button activated models),
- Drive and return spring made of zinc-coated steel wire (springs drive the needles/blades that puncture the skin and retract the needle/blade).

Only the lancet type 520 (*DropSafe Medisafe Solo Safety Lancets*) is not spring-loaded device; the mechanism of lancet activation is operated by "spring-button" element.

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

Sterile, single use medical devices intended for capillary blood sampling.

Technological Characteristics:
[807.92(a)(6)]

A comparison of characteristics of *DropSafe/droplet Safety Lancets* and the predicate device is shown in the table below:

	Subject Devices	**Predicate Device**
Manufacturer	HTL-STREFA S.A	Promisemed Hangzhou Meditech Co., Ltd.
510(k) number	Pending	K192666
Intended use	Sterile, single use medical devices intended for capillary blood sampling	It is intended for capillary blood sampling
Device name	*DropSafe/droplet Safety Lancets:* *DropSafe Acti-Lance Safety Lancets;* *DropSafe ergoLance Safety Lancets;*	*VeriFine Safety Lancet*

		DropSafe Medlance Plus Safety Lancets; *DropSafe Prolance Safety Lancets;* *DropSafe Haemolance Plus Safety Lancets;* *DropSafe Medisafe Solo Safety Lancets;* *droplet ACTI-LANCE Safety Lancets;* *droplet MEDLANCE PLUS Safety Lancets*	
Product code		FMK	FMK
Materials	**Needle/blade**	Needle or blade – medical grade stainless steel	Needle – medical grade stainless steel
	Housing	Plastic resin	Plastic resin
	Spring	Drive and return spring – stainless steel wire	Drive and return spring – stainless steel wire
Operation principle		Manual	Manual
Sharp prevention feature		Yes	Yes
Mechanism of lancet activation		Push-button or contact activation; dual spring mechanism for needle/blade operation	Contact activation; dual spring mechanism for needle operation
Biocompatibility		Conforms to ISO 10993-1	Conforms to ISO 10993-1

Sterility	Sterile; sterilized by gamma irradiation; SAL=10^{-6}	Sterile; sterilized by gamma irradiation
Shelf life	5 years	5 years
Packaging	Cardboard sales box	Cardboard sales box

The new device and the predicate device are classified under 21 CFR § 878.4850, which states: "Single use only blood lancet with an integral sharps injury prevention feature – (1) Identification. 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 integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use."
Based upon the above comparisons to the predicate device, *DropSafe/droplet Safety 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 *DropSafe/droplet Safety Lancets* were performed to demonstrate compliance with the established requirements by manufacturer as per product specifications. These tests were conducted by quality control and include, but are not limited to the following studies: aesthetics and correctness of assembly; no self-activation; lancet activation; minimum puncture; needle/blade retraction after activation.
Additionally non-clinical performance data were obtained after carrying out biocompatibility, sterilization and transport tests. During transport tests, the devices were exposure 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 reports with non-clinical performance data were appended to selected sections of this submission.

Clinical Performance Data:
[(807.92(b)(2)]

The simulated clinical use studies to evaluate sharps injury prevention features of *DropSafe/droplet Safety Lancets* were conducted between 2018 and 2019 in USA.
These tests were conducted by an external agency in accordance with the U.S. Food and Drug Administration's (FDA) guidance on medical devices with sharps injury prevention features (Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features, issued on August 9, 2005). Based on the studies' results, all of tested types of the *DropSafe/droplet Safety Lancets* passed the sharps injury prevention study. The detailed reports describing the mentioned above studies were appended to this submission.

Conclusion: [807.92(b)(3)]

DropSafe/droplet Safety Lancets are substantially equivalent in the intended use, technology/principle of operation, materials and performance to the predicate devices and do not raise any new questions of safety and effectiveness.