September 22, 2022

MediPurpose Pte. Ltd.
% Ms. Julie Stephens
President
Regulatory Resources Group, Inc.
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K222224
Trade/Device Name: SurgiLance® Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: July 25, 2022
Received: July 25, 2022

Dear Ms. Stephens:

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)*
K222224

Device Name
SurgiLance® Safety Lancet

Indications for Use *(Describe)*
The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury. Single patient use only.

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) Summary - 510(k) # K222224

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By:
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Regulatory Resources Group, Inc. - Phone: (678) 513-0693
111 Laurel Ridge Dr, Alpharetta, GA 30004 USA

Date Submitted: September 21, 2022

Device Name and Classification:

Trade/Proprietary Name:	SurgiLance® Safety Lancet
Common Name:	Blood Lancet with Sharps Prevention Feature
Classification Name:	Blood Lancets - Single use only blood lancet with an integral sharps injury prevention feature
Regulation Number:	21 CFR 878.4850
Class:	II
Product Code:	FMK

Legally Marketed Predicate Device:

Primary Predicate: MediPurpose SurgiLance® Safety Lancet, 510(k) # K101145
Additional Predicate: BD Autolancet [Microtainer® Lancet], 510(k) # K822209

Device Description:

The SurgiLance® Safety Lancet is a needle or blade device used to prick a patient's finger to draw a micro-sample of blood which can then be tested for an array of diagnostic assays. Lancets are commonly used in hospitals, clinics, physician offices, laboratories, OB/GYN practices, oncology departments, emergency medical services, nursing homes and blood banks. The outside plastic casing is designed to be ergonomic for the user and compatible with the test site, usually a human finger. The device is available with either a needle or blade, each with different depths of penetration, to provide optimal blood flow for different applications and skin types. The SurgiLance® Safety Lancet comes in seven (7) models: two low flow, two medium flow, and three high flows. The seven models are differentiated by their casing color.

SurgiLance® Safety Lancets are safely retracted and concealed before and after use. The user simply removes the protective cap, places the red raised platform end onto the patient's test site, and gently pushes the lancet down against the test site to activate the lancet mechanism. Once the lancet is used, it is rendered inoperative, providing added safety for patient and clinician. The device is discarded in a sharps container after use. SurgiLance Safety Lancets are provided sterile and are single patient use only. They are sterilized using irradiation (R) sterilization method.

510(k) Summary - 510(k) # K222224

Indications for Use:

The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury. Single patient use only.

The Indications for Use statement for the SurgiLance® Safety Lancet did not change from the cleared 510(k) # K101145. SurgiLance Safety Lancets [Proposed Device and Primary Predicate Device].

Technological Characteristics:

SurgiLance® Safety Lancets [Proposed Device] did not change technological characteristics or material specifications from the cleared 510(k) # K101145 [Primary Predicate Device]. The SurgiLance Safety Lancets are substantially equivalent to the BD Microtainer lancets [Additional Predicate Device] as they have the same basic technology characteristics for piercing the skin with a needle or blade to draw a micro-sample of blood and include a sharps injury prevention feature. The materials are comparable in that the needles and blades all use medical grade stainless steel and the housings are made of medical grade plastics.

Comparison of Technological Characteristics to the Predicate Devices

Proposed Device 510(k) #: Pending	Primary Predicate Device 510(k) #: K101145	Additional Predicate Device 510(k) #: K822209
SurgiLance® Safety Lancet	SurgiLance® Safety Lancet	BD Microtainer® Contact-Activated Lancet
FMK; 21 CFR 878.4850; Class II [New Classification]	FMK; 21 CFR 878.4400; Class I	FMK; 21 CFR 878.4400; Class I
Materials		
Needles -Stainless steels Blades - Stainless steels Housing/Case, Holder, Cap - Plastics	Same - No changes	Needles - Surgical steels Blades - Surgical steels Housing/Case, Holder, Cap - Plastics
Mechanical Specifications		
Low Flow - Needle - G28 & G21 Medium Flow - Needle - G21 High Flow - Blade - G21 & G18	Same - No changes	Low Flow - Needle - G30 Medium Flow - Needle - G21 High Flow - Blade 1.5mm/G16.5
Labeled Cut Profiles: Cut Depths (mm) and Blood Flow		
Low Flow - 1.7& 1.0 depths Medium Flow - 1.8 & 2.2 depths High Flow - 2.8, 1.8 & 2.3 depths	Same - No changes	Low Flow - 1.5 depth (single drop) Medium Flow - 1.8 depth High Flow - 2.0 depth

510(k) Summary - 510(k) # K222224

Proposed Device 510(k) #: Pending	Primary Predicate Device 510(k) #: K101145	Additional Predicate Device 510(k) #: K822209
Safety Features		
• Single use only with an integral sharps injury prevention feature. • Needle/blade is not exposed except when lancet is activated. • The needle/blade retracts back into the housing at the end of the incision motion; the trigger mechanism is disabled and locks the needle/blade in the housing.	Same - No changes	• Single use only with an integral sharps injury prevention feature. • Needle/blade is not exposed except when lancet is activated. • The needle/blade retracts back into the housing at the end of the incision motion; the trigger mechanism is disabled and locks the needle/blade in the housing.

Summary of Testing:

The biocompatibility risk assessment was completed as directed by FDA guidance under ISO 10993-1 biocompatibility requirements. Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, and Hemolysis testing was completed to demonstrate that the known biocompatible materials maintained compliance through manufacturing and sterilization. Performance and safety testing completed for the SurgiLance® Safety Lancet included tests for drop testing, trigger force and reverse safety, penetration and depth force measurements, and simulated use testing.

Substantial Equivalence Conclusions:

SurgiLance® Safety Lancets have the same principles of operation, intended use, and technological characteristics including the materials used, mechanical specifications, cutting profiles, and sharps injury prevention features as the predicate devices. The sharps prevention feature was fully tested to the FDA's guidance document as demonstrated in the performance testing.