10/25/2022

Owen Mumford Ltd
% Patty Cronan
Quality Manager
Owen Mumford USA Inc.
1755 West Oak Commons Ct.
Marietta, Georgia 30062

Re: K222303
Trade/Device Name: Unistik® Pro
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: July 27, 2022
Received: August 1, 2022

Dear Patty Cronan:

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

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)*
K222303

Device Name
Unistik Pro

Indications for Use *(Describe)*
The intended user is any patient that needs to obtain capillary samples at home/clinical environment. Unistik Pro is a single-use lancet used to obtain a capillary blood sample.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5.0

510(k) SUMMARY

1. Submitter

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Date Prepared: 27th July 2022

2. Device

510(k) Number:	**K222303**
Name of Device:	Unistik® Pro
Common Name:	Blood lancets
Classification Name:	Single use only blood lancet with an integral sharps injury prevention feature
Regulatory Class:	II
Product Code:	FMK

3. Predicate Devices

Predicate Device Name: SurgiLance® Safety Lancet, under 510k number K101145.

(Cleared for: Prescription Use and Over-The-Counter Use)

4. Description of The Device

The Unistik® Pro is a sterile single-use safety lancet, a hand-held disposable device intended to be used to achieve a controlled skin puncture on the fingertip, in order to obtain a capillary blood specimen. The Unistik® Pro sterile single-use safety lancets are indicated for use where a capillary blood specimen is required for the purposes of performing in-vitro diagnostic (IVD) assays, e.g., for blood glucose monitoring in patients with diabetes.

The Unistik® Pro safety lancets are available in 3 different variants, each with a different needle gauge (21G, 25G and 28G with penetration depths of 2.0mm, 1.6mm and 1.2mm respectively) as required by the patient.

The Unistik® Pro sterile single-use safety lancets are designed for prescription and over-the-counter use and to be used by self-testing patients, care-givers and healthcare professionals. The devices are designed to perform a controlled skin puncture on the fingertip, in order for care-givers and healthcare professionals to obtain capillary blood specimens from patients for IVD assays, and also for lay (home) users to be able to perform a skin puncture on themselves where an IVD self-testing regime is required. The intended user population includes male and female, right or left-handed self-administering patients, care givers and healthcare professionals. The frequency of use and intended patient population is dependent on the given diagnostic regime.

The Unistik® Pro sterile single-use safety lancets feature integral sharps protection whereby the lancet needle is shielded before and after use to prevent needlestick injuries, so mitigating the hazard of transmission of blood-borne infectious agents. Furthermore, the device automatically self-disables after a single use, thus preventing any hazards of re-use.

The purpose of these 510(k) applications is to obtain both prescription-only clearance and over-counter clearance for the Unistik® Pro sterile single-use safety lancets. The intended use for the Unistik® Pro sterile single use safety lancets is similar and substantially equivalent to the predicate device.

Note: The Unistik® Pro was previously produced for Owen Mumford by Artaplast, and as such some of the documentation supplied to support this submission may reference the company "Artaplast". In addition, in Artaplast documentation the device may be referred to as the following previously used names: "Carelance Micro Flow", "Optilance Micro Flow", "Arta Lancet". In some Owen Mumford documentation, Unistik Pro may be referred to as "Unistik Protop". All of the references listed in this note can be considered to refer to the Unistik Pro device produced by Owen Mumford Ltd for the entirety of this submission.

5. Indications for Use

The intended user is any patient that needs to obtain capillary samples at home/clinical environment. Unistik Pro is a single-use lancet used to obtain a capillary blood sample.

6. Technological Characteristics

The Unistik® Pro sterile single-use safety lancets are substantially equivalent to the predicate device, the SurgiLance® Safety Lancet, 510(k) number **K101145**.

A comparison of the intended uses and technological characteristics of the Unistik® Pro sterile single-use safety lancets to the predicate SurgiLance® devices is summarized in table 5.1 below.

Table 5.1 A comparison of the device characteristics between the predicate and submission devices

Device Characteristic	**Predicate Device: SurgiLance® Safety Lancets – K101145.**	**Submission Device - Unistik® Pro sterile single-use safety lancets**
Intended Use	The SurgiLance® Safety Lancet is a skin puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from needlestick injuries.	The intended user is any patient that needs to obtain capillary samples at home/clinical environment. Unistik Pro is a single-use lancet used to obtain a capillary blood sample. Therefore, substantially equivalent to the predicate device
Use environment	Home and clinical	Home and clinical
Operating principle	Contact-activated spring-powered automatic lancing and needle retraction.	Manually activated (rear fire button) spring-powered automatic lancing and needle retraction.
Design/ construction	Stainless steel lancet needle moulded into a plastic lancet holder component, which in turn is assembled into a moulded plastic outer housing with a pre-loaded steel spring	Similar to the predicate device, consisting of stainless steel lancet needle moulded into plastic lancet holder component, assembled into a moulded plastic outer housing with a steel spring, additionally with a plastic rear firing button
Integral sharps injury prevention feature?	Yes	Unchanged from the predicate device
Single-use?	Yes	Unchanged from the predicate device
Sterility	Sterile	Unchanged from the predicate device
Components and Materials	Plastic external and internal components, stainless steel needle and steel spring	Unchanged from the predicate device, but likely that plastic and steel specifications used differ from predicate.
Package	Laminate pulp board cartons	Unchanged from the predicate device.

Device Characteristic		**Predicate Device: SurgiLance® Safety Lancets – K101145.**	**Submission Device - Unistik® Pro sterile single-use safety lancets**
Needle Specifications	Needle Gauges (SWG)	18G, 21G	21G, 25G and 28G The predicate device is available in 18G and 21G variants only, therefore the Unistik® Pro sterile single-use safety lancets represent an extended range of higher gauges (smaller needle diameters) compared to the predicate.
	Lancing Depths (mm)	1.8 mm & 2.3 mm (18G) 1.0 mm, 1.8 mm, 2.2 mm & 2.8 mm (21G)	2.0mm (21G), 1.6mm (25G) and 1.2mm (28G) The Unistik® Pro sterile single-use safety lancets lancing depth range falls within the range offered by the predicate device, i.e. 1.2mm – 2.0mm (Unistik Pro) compared to the predicate range of 1.0mm – 2.
	Sterilisation method	Not known.	25-60 kGy electron beam irradiation validated to achieve a sterility assurance level (SAL) of 10^{-6}.

7. Performance Data

Non-clinical performance data:

Design verification testing of the Unistik® Pro sterile single-use safety lancets has been carried out to evaluate the performance of the devices against defined acceptance criteria.

The following table provides a summary of the relevant design verification testing.

Bench Testing:

Table 5.1: Summary of the performance tests performed on Unistik Pro

Test	Requirement	Results
Needle Retention Force	Internal test specification	Meets specification
Depth of Penetration	Internal test specification	Meets specification
Sharps Injury Protection	Internal test specification	Meets specification
Button Activation Force	Internal test specification	Meets specification
Cap Removal Torque	Internal test specification	Meets specification
Drop test (as part of sharps injury protection test)	Internal test specification	Meets specification

The devices comply with the acceptance criteria established based on the specifications of the devices. All additional performance tests met the acceptance criteria.

The results from these tests demonstrate that the Unistik® Pro sterile single-use safety lancets are safe and effective when used as intended.

Biocompatibility:

Based on available information and biocompatibility reports available for the device and its components, Owen Mumford concludes that the device meets all requirements according to ISO 10993 and FDA guidance when used as intended.

Please see **Section 15 – Biocompatibility** for more information.

Sterilisation:

The sterility of the devices is assured using a sterilisation method validated in accordance with ISO 11137 “Medical Devices – Validation and Routine Control of Radiation Sterilisation”. Through the sterilisation methods used, all devices are sterilised to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Sterilization Method: Electron beam irradiation

Radiation dose range: 25-60 kGy

Sterility assurance level (SAL): 10^{-6}

Shelf life

The Unistik® Pro sterile barrier has been qualified for 5 years, but Owen Mumford is currently submitting Unistik Pro with a 2.5-year shelf life, with a plan to supplement this submission with accelerated-aged functional testing data in the near future. For more information see Section 18 – Performance Testing.

8. Conclusion

In summary, the differences between the Unistik® Pro sterile single-use safety lancets and the predicate device have no impact on safety and effectiveness and the products are therefore substantially equivalent to the predicate device.