September 7, 2022

Owen Mumford Ltd
Darren Mansell
Regulatory Affairs Manager
Brook Hill
Woodstock, Oxfordshire OX20 1TU
United Kingdom

Re: K222111
Trade/Device Name: Unistik Touch Single-Use Safety Lancets - 16G, 21G, 23G, 28G and 30G
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: July 11, 2022
Received: July 18, 2022

Dear Darren Mansell:

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

# SECTION 4.0

# INDICATIONS FOR USE STATEMENT

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)*
K222111

Device Name
Unistik® Touch

Indications for Use *(Describe)*

The Unistik® Touch is a puncture device to obtain micro blood samples. Unistik Touch has a sharps prevention feature to protect the user from a needlestick injury.

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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# SECTION 5.0

# 510(k) SUMMARY

# SECTION 5.0

# 510(k) SUMMARY

## 1. Submitter


Prepared by: Owen Mumford Ltd
Tel: +44(0)1993 812021
Fax: +44(0)1993 813466

Prepared for: **Owner/ Operator**
Owen Mumford Ltd
Brook Hill
Woodstock
Oxfordshire
OX20 1TU
United Kingdom
Establishment Registration Number: 3003348846

Contact Person: Darren Mansell
Regulatory Affairs Manager
Owen Mumford Ltd,
Tel: +44(0)1993 812021
Fax: +44(0)1993 813466
Email: darren.mansell@owenmumford.com


Date Prepared: JULY 11, 2022

## 2. Device

Name of Device: Unistik® Touch Sterile Single-Use Contact-Activated Safety Lancets

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 Names**:

SurgiLance® Safety Lancet

The Unistik® Touch sterile single-use contact activated safety lancets are substantially equivalent in device description, function and basic composition of materials to the predicate device, SurgiLance® Safety Lancet, under 510k number K101145.

## 4. Description of The Device

The Unistik® Touch contact-activated safety lancets are hand-held disposable devices intended for performing controlled skin punctures of the fingertips in adults and children, by means of a needle lancing mechanism.

Unistik® Touch 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® Touch contact-activated safety lancets are available in five different variants of needle gauge as follows:

Needle gauge 16G, Penetration Depth 2.0 mm

Needle gauge 21G, Penetration Depth 2.0 mm

Needle gauge 23G, Penetration Depth 2.0 mm

Needle gauge 28G, Penetration Depth 1.8 mm

Needle gauge 30G, Penetration Depth 1.5 mm

The Unistik® Touch contact-activated safety lancets are intended 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.

Unistik® Touch contact-activated safety lancets are sterile single-use devices with integral sharps protection whereby the lancet blade or needle is shielded before and after use to prevent needlestick injuries, so mitigating the hazard of transmission of blood-borne infectious agents. Furthermore, the devices automatically self-disable after a single use, thus preventing any hazards of re-use.

The Unistik® Touch contact-activated safety lancets achieve their intended purpose of performing controlled skin punctures of the fingertips in adults and children, by means of a needle lancing mechanism with a pre-loaded steel spring for propelling the lancet holder forward when the device is activated and subsequently automatically retracting it. After retraction, the lancet holder is automatically locked into the device such that the device cannot be re-used and the needle tip is safely shielded.

The lancet needles are moulded into the lancet holder component such that the needle tip is sealed by complete encapsulation in overmoulded plastic. The complete lancet holder component is then sterilised by gamma irradiation, so after irradiation the sterility of the needle tip is maintained by encapsulation within the plastic. The sterile seal is only broken when the user twists off and removes the lancet cap immediately before use. The needle tip is the exposed needle length after the cap is removed, and this is the only part of the needle that will penetrate the patient's skin during use. Therefore, the encapsulation of the needle tip by plastic overmoulding performs the function of primary packaging, whereby a sterile seal is maintained until the point of use.

## 5. Indications for Use

The Unistik® Touch is a puncture device to obtain micro blood samples. Unistik Touch has a sharps prevention feature to protect the user from a needlestick injury.

## 6. Technological Characteristics

The Unistik® Touch contact-activated safety lancets are substantially equivalent to the predicate device, the SurgiLance® Safety Lancet.

Table 6.1 below summarise a comparison of the intended uses and technological characteristics of the Unistik® Touch device to the respective predicate.

Table 6.1 – Comparison of the Unistik® Touch submission device to the SurgiLance® predicate device

| Device Characteristic | Predicate Device: SurgiLance® Safety Lancets – K101 145. | Submission Device - Unistik® Touch Safety Lancets |
|---|---|---|
| Intended Use | The SurgiLance® Safety Lancet is a skin puncture device to obtain micro blood samples.<br><br>The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from needlestick injuries. | Unchanged from the predicate device. |
| Use environment | Home and clinical | Unchanged from the predicate device. |
| Operating principle | Contact-activated spring-powered automatic lancing and needle retraction. | Unchanged from the predicate device. |
| 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 | Unchanged from the predicate device. |
| 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 |

| Device Characteristic | Predicate Device: SurgiLance® Safety Lancets – K101 145. | Submission Device - Unistik® Touch Safety Lancets |
|---|---|---|
| Sterilisation method | Irradiation | 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. |
| Needle Gauges (SWG) | 18G, 21G | 16G, 21G, 23G, 28G, 30G<br><br>The predicate device is available in 18G and 21G variants only, whereas the Unistik® Touch devices represent an extended range of gauges compared to the predicate (16G – 30G). |
| Lancing Depths (mm) | 1.8 mm & 2.3 mm (18G)<br><br>1.0 mm, 1.8 mm, 2.2 mm & 2.8 mm (21G) | 2.0 mm (16G, 21G and 23G)<br><br>1.8 mm (28G)<br><br>1.5 mm (30G)<br><br>Substantially equivalent to the predicate device – the Unistik® Touch lancing depth range falls within the range offered by the predicate device, i.e. 1.0 mm - 2.0 mm compared to the predicate range of 1.0 mm - 2.8 mm. |

## 7. Performance Data

**Non-clinical performance data:**

Design verification testing of the Unistik® Touch 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:**

The bench testing performed verifies that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device, in terms of critical performance characteristics. These tests are as follow.

| Items | Acceptance criteria | Results |
|---|---|---|
| Appearance | The surface shall be free of burrs and no scratches shall be visible | Pass |
| Dimension | Product dimensions shall be consistent to the drawings | Pass |
| Cleanness | No dust, no grease, no hair, no dirt | Pass |
| Firmness | Needle should connect firmly with plastic handle | Pass |
| Resistance to corrosion | Needle of lancet shall show no evidence of corrosion. | Pass |
| Acidity or Alkalinity | The pH value of an extract prepared refers to ISO 9626 Annex A shall be within one pH unit of that of the control fluid. | Pass |
| Limits for Extractable Metals | When corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0.1 mg/l. | Pass |
| Puncture depth | Use calipers to measure and meet the requirements. | Pass |

| | | |
|---|---|---|
| Launch performance | Launch performance should be good, launch button press smoothly, no jam | Pass |
| Puncture force | The needle tip of the needle should have good puncture ability. | Pass |
| Lubricant | No lubricant shall be visible. | Pass |
| Disposable | Safety lancet should be single use, and should not be operational after use | Pass |
| Drop Test | The needle tip shall not be exposed after dropping the device vertically from a height of 1.2m | Pass |
| Safety Feature | The force to activate the safety feature: 4 - 15N<br>Test access to the needle: the needle shall not touch the sphere. | Pass |

The results from these tests demonstrate that the Unistik® Touch devices are safe and effective when used as intended.

**Biocompatibility:**

Biocompatibility evidence per ISO 10993-1 is available, to demonstrate the device is safe for its intended use.

**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 $10^{-6}$.

**Simulated Clinical Use:**

A simulated clinical use study was performed on 500 device samples each for the Safety Lancet according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005 and ISO 23908 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

## 8. Conclusion

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