11/3/2022

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

Re: K222168
Trade/Device Name: Unistik TinyTouch Sterile Single-Use Heel Incision Safety Lancets - Preemie and Full-Term, Unistik Heelstik Sterile Single-Use Heel Incision Safety Lancets - MicroPreemie, Preemie, Full-Term and Toddler
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: July 15, 2022
Received: July 21, 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,

Jessica Carr -S

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)*
K222168

Device Name
Unistik® TinyTouch, Unistik® Heelstik

Indications for Use *(Describe)*

Unistik® Heelstik:

The Unistik® Heelstik heel incision safety lancets are single use devices used to collect a capillary blood sample from the heel of newborns, preemies, and toddlers.

Unistik® TinyTouch:

The Unistik® TinyTouch heel incision safety lancets are single use devices used to collect a capillary blood sample from the heel of newborns, preemies, and toddlers.

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

1. Submitter

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Date Prepared: 03 November 2022

2. Device

Name of Device: Unistik® TinyTouch Sterile Single-Use Heel Incision Safety Lancets

Unistik® Heelstik Sterile Single-Use Heel Incision 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:

SteriHeel Heel Incision Safety Lancet –

The Unistik® TinyTouch sterile single-use heel incision safety lancets and Unistik® Heelstik sterile single-use heel incision safety lancets are substantially equivalent in device description, function, and basic composition of materials to the predicate device, the SteriHeel Heel Incision Safety Lancet under 510k number K210745.

4. Description of The Device

The submission devices 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. The devices automatically self-disable after a single use, thus preventing any hazards of re-use.

The submission devices are intended for use by healthcare professionals only, for performing heel incisions on newborns, preemies, and toddlers to obtain capillary blood specimens for IVD assays. The product is intended for prescription (Rx) only use.

5. Indications for Use

The Unistik® Heelstik heel incision safety lancets are single use devices used to collect a capillary blood sample from the heel of newborns, preemies, and toddlers.

The Unistik® TinyTouch heel incision safety lancets are single use devices used to collect a capillary blood sample from the heel of newborns, preemies, and toddlers.

6. Technological Characteristics

The Unistik® TinyTouch and Unistik® Heelstik sterile single-use heel incision safety lancets are substantially equivalent to the predicate device, the SteriHeel Heel Incision Safety Lancet.

Tables 6.1 and 6.2 below summarise a comparison of the intended uses and technological characteristics of the Unistik® TinyTouch and Unistik® Heelstik and Unistik® Touch devices to the predicates.

Table 6.1 – Comparison of the Unistik® TinyTouch submission device to the SteriHeel predicate device

Device Characteristic	**Predicate Device: SteriHeel Heel Incision Safety Lancets – K210745.**	**Submission Device - Unistik® TinyTouch Heel Incision Safety Lancets**
Intended Use	The SteriHeel Safety Lancet is a heel incision device to obtain capillary blood samples from newborns, premature babies and toddlers The SteriHeel Safety Lancet has a sharps prevention feature to protect the user from needlestick injuries.	Unchanged from the predicate device.
Use environment	Clinical	Unchanged from the predicate device.
Operating principle	Trigger button-activated, spring-powered automatic sweeping blade incision and blade lockout	Unchanged from the predicate device.
Design/ construction	Stainless steel blade moulded into a plastic 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

Device Characteristic	Predicate Device: SteriHeel Heel Incision Safety Lancets – K210745.	Submission Device - Unistik® TinyTouch Heel Incision Safety Lancets
Sterility	Sterile	Unchanged from the predicate device
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.
Incision dimensions	Depth*Length: 0.65*1.40mm 0.85*1.75mm 1.00*2.50mm 1.14*2.80mm 2.00*3.00mm	Substantially equivalent to the predicate device – the incision dimensions are within the range achieved by the predicate device Depth*Length: Preemie – 0.85*1.75 Full Term – 1.00*2.50

Table 6.2 – Comparison of the Unistik® Heelstik submission device to the SteriHeel predicate device

Device Characteristic	**Predicate Device: SteriHeel Heel Incision Safety Lancets – K210745.**	**Submission Device - Unistik® Heelstik Heel Incision Safety Lancets**
Intended Use	The SteriHeel Safety Lancet is a heel incision device to obtain capillary blood samples from newborns, premature babies and toddlers The SteriHeel Safety Lancet has a sharps prevention feature to protect the user from needlestick injuries.	Unchanged from the predicate device.
Use environment	Clinical	Unchanged from the predicate device.
Operating principle	Trigger button-activated, spring-powered automatic sweeping blade incision and blade lockout	Unchanged from the predicate device.
Design/ construction	Stainless steel blade moulded into a plastic 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
Sterilisation method	Irradiation	Unchanged from the predicate device

Device Characteristic	Predicate Device: SteriHeel Heel Incision Safety Lancets – K210745.	Submission Device - Unistik® Heelstik Heel Incision Safety Lancets
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.
Incision dimensions	Depth*Length: 0.65*1.40mm 0.85*1.75mm 1.00*2.50mm 1.14*2.80mm 2.00*3.00mm	Substantially equivalent to the predicate device – the incision dimensions are within the range achieved by the predicate device Depth*Length: Micro Preemie 0.65mm*1.5mm Preemie 0.85*1.75 Full Term 1.0*2.5 Toddler 1.5*2.8

7. Performance Data

Non-clinical performance data:

Design verification testing of the Unistik® TinyTouch and Unistik® Heelstik heel incision safety lancets has been carried out to evaluate the performance of the devices against defined acceptance criteria.

Bench Testing:

Tables 7.1 and 7.2 below provide a summary of the relevant bench testing for the Unistik® TinyTouch and Unistik® Heelstik devices respectively.

Table 7.1 – Summary of bench testing for the Unistik® TinyTouch device

Test	**Results**
Sterility tab removal force	Meets acceptance criteria/ Pass
Button actuation force	Meets acceptance criteria/ Pass
Trigger interlock resistance force	Meets acceptance criteria/ Pass
Side load function test	Meets acceptance criteria/ Pass
Incision profile – depth of cut	Meets acceptance criteria/ Pass
Incision profile – length of cut	Meets acceptance criteria/ Pass
Simulated storage conditions (8 hour storage at 60°C/0% relative humidity, -20° C / 0% relative humidity)	Meets acceptance criteria/ Pass
Simulated contact conditions (cleaned/wiped with 70% isopropyl alcohol)	Meets acceptance criteria/ Pass
Drop test	Meets acceptance criteria/ Pass
Sterile barrier integrity test	Meets acceptance criteria/ Pass
Shipping test report	Meets acceptance criteria/ Pass

Table 7.2- :Summary of bench testing for the Unistik® Heelstik device

Test	**Results**
Appearance	Meets acceptance criteria/ Pass
Blood collection function	Meets acceptance criteria/ Pass
Assembly status	Meets acceptance criteria/ Pass
Dimension	Meets acceptance criteria/ Pass
Resistance to corrosion	Meets acceptance criteria/ Pass
Acidity or Alkalinity	Meets acceptance criteria/ Pass
Extractable Metals	Meets acceptance criteria/ Pass
Structural integrity	Meets acceptance criteria/ Pass
Resistance to re-use	Meets acceptance criteria/ Pass
Incision profile – depth and length	Meets acceptance criteria/ Pass
Drop test	Meets acceptance criteria/ Pass
Packaging test after accelerated aging	Meets acceptance criteria/ Pass
Performance test after accelerated aging	Meets acceptance criteria/ Pass
Simulated clinical study	Meets acceptance criteria/ Pass

Additionally, performance testing other than the above was conducted on the devices. 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® TinyTouch and Unistik® Heelstik heel incision safety lancets are safe and effective when used as intended.

Biocompatibility:

Biocompatibility evidence per ISO 10993-1 is available for the materials of Unistik® TinyTouch and Unistik® Heelstik heel incision safety lancets.

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}.

8. Conclusion

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