June 30, 2023

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

Re: K223854
Trade/Device Name: Unistik® ShieldLock, Unistik® VacuFlip
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, FPA, FMI
Dated: May 30, 2023
Received: June 1, 2023

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,

Patricia Bennett

For David Wolloscheck, Ph.D.
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K223854

Device Name
Unistik® ShieldLock, Unistik® VacuFlip

Indications for Use *(Describe)*
Unistik® ShieldLock: The Unistik ShieldLock Blood Collection Set is a sterile, multi-sample, single-use 'butterfly' style blood collection set intended to be used by trained healthcare professionals for venipuncture to obtain blood specimens from patients into blood collection tubes or blood culture bottles. When used without the male adapter, the device allows the clinician to obtain a blood specimen from the female hub with a syringe.

Unistik® VacuFlip: The Unistik VacuFlip Safety Blood Collection Needle is intended to be used by healthcare professionals with vacuum blood collection tubes for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick 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.**

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# 510(k) SUMMARY – K223854

## 1. Submitter


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**Date Prepared:** 06/30/2023

## 2. Subject Device

| | |
|---|---|
| Trade Name: | Unistik® ShieldLock<br>Unistik® VacuFlip |
| Regulation Number: | 21 CFR 862.1675 |
| Common Name: | Blood collection sets |
| Regulation Name: | Blood Specimen Collection Device |
| Regulatory Class: | Class II |
| Product Code(s): | JKA, FPA, FMI |

## 3. Predicate Device(s)

**Predicate Device #1** - 510k number **K212724**.

| | |
|---|---|
| Trade Name: | BD Vacutainer® UltraTouch™ push button blood collection set |
| Regulation Number: | 21 CFR 862.1675 |
| Common Name: | Blood collection sets |
| Regulation Name: | Blood Specimen Collection Device |
| Regulatory Class: | Class II |
| Product Code: | JKA, FPA |

**Predicate Device #2** - 510k number **K982541**

| | |
|---|---|
| Trade Name: | Vacutainer® Brand Eclipse™ Blood Collection Needle |
| Regulation Number: | 21 CFR 880.5570 |
| Common Name: | Blood collection needle |
| Regulation Name: | Needle, hypodermic, single lumen |
| Regulatory Class: | Class II |
| Product Code: | FMI |

## 4. Description of The Devices

The Unistik® ShieldLock is a sterile, single use, multi-sample blood collection set for use by healthcare professionals to obtain venous blood specimens from patients when used in conjunction with blood collection tubes or syringes. The Unistik Shield Lock is a 'butterfly needle' with wings, the color of the wings is unique for each needle gauge to assist with identification. The Unistik ShieldLock is designed for prescription use only and is to be used only by healthcare professionals for patients who are required to have venous blood specimens collected.

The Unistik® VacuFlip is a sterile, single use, multi-sample blood collection vacuum needle for use by healthcare professionals to obtain venous blood specimens from patients when used in conjunction with blood collection tubes or syringes. The Unistik VacuFlip is a 'vacuum needle' and is designed with a user activated integral sharps injury prevention feature, the safety shield, which can be activated after the needle is removed from the vein to help prevent needlestick injuries. The safety shield features a textured surface to help improve grip during activation. An audible click signals that the safety shield is activated and is locked in place, covering the needle, and preventing reuse. The color of the safety shield is unique for each needle gauge to assist with identification. The Unistik VacuFlip is designed for prescription use only and is to be used only by healthcare professionals for patients who are required to have venous blood specimens collected.

Please see table 5.1 overleaf for a list of all available device models.

***Table 5.1 List of all available device models***

| Device Name | Configuration | Variant | Box Qty. | Product Code |
|---|---|---|---|---|
| **Unistik ShieldLock** | Blood Collection Set with Luer Adapter | 20G Needle, 19mm needle length, 200mm tube and with Luer attached. No vacuum holder. | 100 | P003763A1 |
| | Blood Collection Set without Luer Adapter | 20G Needle, 19mm needle length, 200mm tube and without Luer or vacuum holder. | 100 | P003764A1 |
| | Blood Collection Set with Pre-Attached Holder | 20G Needle, 19mm needle length, 200mm tube, with Luer and vacuum holder attached. | 50 | P003765A1 |
| | Blood Collection Set with Luer Adapter | 20G Needle, 19mm needle length, 300mm tube and with Luer attached. No vacuum holder. | 100 | P003766A1 |
| | Blood Collection Set without Luer Adapter | 20G Needle, 19mm needle length, 300mm tube and without Luer or vacuum holder. | 100 | P003767A1 |
| | Blood Collection Set with Pre-Attached Holder | 20G Needle, 19mm needle length, 300mm tube, with Luer and vacuum holder attached. | 50 | P003768A1 |
| | Blood Collection Set with Luer Adapter | 21G Needle, 19mm needle length, 200mm tube and with Luer attached. No vacuum holder. | 100 | P003769A1 |
| | Blood Collection Set without Luer Adapter | 21G Needle, 19mm needle length, 200mm tube and without Luer or vacuum holder. | 100 | P003770A1 |
| | Blood Collection Set with Pre-Attached Holder | 21G Needle, 19mm needle length, 200mm tube, with Luer and vacuum holder attached. | 50 | P003771A1 |
| | Blood Collection Set with Luer Adapter | 21G Needle, 19mm needle length, 300mm tube and with Luer attached. No vacuum holder. | 100 | P003772A1 |
| | Blood Collection Set without Luer Adapter | 21G Needle, 19mm needle length, 300mm tube and without Luer or vacuum holder. | 100 | P003773A1 |
| | Blood Collection Set with Pre-Attached Holder | 21G Needle, 19mm needle length, 300mm tube, with Luer and vacuum holder attached. | 50 | P003774A1 |
| | Blood Collection Set with Luer Adapter | 22G Needle, 19mm needle length, 200mm tube and with Luer attached. No vacuum holder. | 100 | P003775A1 |
| | Blood Collection Set without Luer Adapter | 22G Needle, 19mm needle length, 200mm tube and without Luer or vacuum holder. | 100 | P003776A1 |
| | Blood Collection Set with Pre-Attached Holder | 22G Needle, 19mm needle length, 200mm tube, with Luer and vacuum holder attached. | 50 | P003777A1 |
| | Blood Collection Set with Luer Adapter | 22G Needle, 19mm needle length, 300mm tube and with Luer attached. No vacuum holder. | 100 | P003778A1 |

| Device Name | Configuration | Variant | Box Qty. | Product Code |
|---|---|---|---|---|
| **Unistik ShieldLock** | Blood Collection Set without Luer Adapter | 22G Needle, 19mm needle length, 300mm tube and without Luer or vacuum holder. | 100 | P003779A1 |
| | Blood Collection Set with Pre-Attached Holder | 22G Needle, 19mm needle length, 300mm tube, with Luer and vacuum holder attached. | 50 | P003780A1 |
| | Blood Collection Set with Luer Adapter | 23G Needle, 19mm needle length, 200mm tube and with Luer attached. No vacuum holder. | 100 | P003781A1 |
| | Blood Collection Set without Luer Adapter | 23G Needle, 19mm needle length, 200mm tube and without Luer or vacuum holder. | 100 | P003782A1 |
| | Blood Collection Set with Pre-Attached Holder | 23G Needle, 19mm needle length, 200mm tube, with Luer and vacuum holder attached. | 50 | P003783A1 |
| | Blood Collection Set with Luer Adapter | 23G Needle, 19mm needle length, 300mm tube and with Luer attached. No vacuum holder. | 100 | P003784A1 |
| | Blood Collection Set without Luer Adapter | 23G Needle, 19mm needle length, 300mm tube and without Luer or vacuum holder. | 100 | P003785A1 |
| | Blood Collection Set with Pre-Attached Holder | 23G Needle, 19mm needle length, 300mm tube, with Luer and vacuum holder attached. | 50 | P003786A1 |
| | Blood Collection Set with Luer Adapter | 25G Needle, 19mm needle length, 200mm tube and with Luer attached. No vacuum holder. | 100 | P003787A1 |
| | Blood Collection Set without Luer Adapter | 25G Needle, 19mm needle length, 200mm tube and without Luer or vacuum holder. | 100 | P003788A1 |
| | Blood Collection Set with Pre-Attached Holder | 25G Needle, 19mm needle length, 200mm tube, with Luer and vacuum holder attached. | 50 | P003789A1 |
| | Blood Collection Set with Luer Adapter | 25G Needle, 19mm needle length, 300mm tube and with Luer attached. No vacuum holder. | 100 | P003790A1 |
| | Blood Collection Set without Luer Adapter | 25G Needle, 19mm needle length, 300mm tube and without Luer or vacuum holder. | 100 | P003791A1 |
| | Blood Collection Set with Pre-Attached Holder | 25G Needle, 19mm needle length, 300mm tube, with Luer and vacuum holder attached. | 50 | P003792A1 |
| **Unistik VacuFlip** | Blood Collection Safety Needle with Pre-Attached Holder | 21G 1-1/4" Needle with Pre-Attached Holder | 50 | P004823A1 |
| | Blood Collection Safety Needle with Pre-Attached Holder | 22G 1-1/4" Needle with Pre-Attached Holder | 50 | P004825A1 |

| Device Name | Configuration | Variant | Box Qty. | Product Code |
|---|---|---|---|---|
| **Unistik VacuFlip** | Blood Collection Safety Needle with Pre-Attached Holder | 21G 1-1/2" Needle with Pre-Attached Holder | 50 | P004824A1 |
| | Blood Collection Safety Needle with Pre-Attached Holder | 22G 1-1/2" Needle with Pre-Attached Holder | 50 | P004826A1 |
| | Blood Collection Safety Needle with Pre-Attached Holder | 21G 1" Needle with Pre-Attached Holder | 50 | P003793A1 |
| | Blood Collection Safety Needle with Pre-Attached Holder | 22G 1" Needle with Pre-Attached Holder | 50 | P003794A1 |
| | Blood Collection Safety Needle with Pre-Attached Holder | 20G 1-1/4" Needle with Pre-Attached Holder | 50 | P003795A1 |
| | Blood Collection Safety Needle with Pre-Attached Holder | 20G 1-1/2" Needle with Pre-Attached Holder | 50 | P003796A1 |
| | Blood Collection Safety Needle with Pre-Attached Holder | 20G 1" Needle with Pre-Attached Holder | 50 | P003797A1 |
| | Blood Collection Safety Needle | 21G 1-1/4" Needle with Luer | 100 | P004819A1 |
| | Blood Collection Safety Needle | 22G 1-1/4" Needle with Luer | 100 | P004821A1 |
| | Blood Collection Safety Needle | 21G 1-1/2" Needle with Luer | 100 | P004820A1 |
| | Blood Collection Safety Needle | 22G 1-1/2" Needle with Luer | 100 | P004822A1 |
| | Blood Collection Safety Needle | 20G 1-1/4" Needle with Luer | 100 | P003798A1 |
| | Blood Collection Safety Needle | 20G 1-1/2" Needle with Luer | 100 | P003805A1 |

| Device Name | Configuration | Variant | Box Qty. | Product Code |
|---|---|---|---|---|
| **Unistik VacuFlip** | Blood Collection Safety Needle | 20G 1" Needle with Luer | 100 | P003806A1 |
| | Blood Collection Safety Needle | 21G 1" Needle with Luer | 100 | P003807A1 |
| | Blood Collection Safety Needle | 22G 1" Needle with Luer | 100 | P003808A1 |

## 5. Indications for Use

Unistik® ShieldLock: The Unistik ShieldLock Blood Collection Set is a sterile, multi-sample, single-use 'butterfly' style blood collection set intended to be used by trained healthcare professionals for venipuncture to obtain blood specimens from patients into blood collection tubes or blood culture bottles. When used without the male adapter, the device allows the clinician to obtain a blood specimen from the female hub with a syringe.

Unistik® VacuFlip: The Unistik VacuFlip Safety Blood Collection Needle is intended to be used by healthcare professionals with vacuum blood collection tubes for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury.

## 6. Technological Characteristics

The technical characteristics for the subject device and the predicate devices are shown below in Tables 5.2 and 5.3.

*Table 5.2: Comparison of the technical characteristics between the subject device Unistik ShieldLock and the predicate device*

| **Test/ Characteristic** | **Predicate Device:** **BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, K212724** | **Subject Device:** **Unistik® ShieldLock** | **Comparison** |
|---|---|---|---|
| Patient Target Group | General use including patients with difficult vein access (DVA) | General use | Specific reference to DVA has no effect on device safety/effectiveness as DVA is a subset of general use |
| Indications for Use Statement | Indications for Use (Describe):<br>The BD Vacutainer® UltraTouch™ Push Button Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended to be used by trained healthcare professionals for venipuncture to obtain blood specimens from patients, including those patients with difficult vein access who may have small, fragile, and/or non-palpable veins, into evacuated blood collection tubes and/or blood culture bottles. When used without the male adapter, the device allows the clinician to obtain a blood specimen from the female hub with a syringe, if necessary. The device can be used for short-term, single | Indications for Use (Describe):<br>The Unistik ShieldLock Blood Collection Set is a sterile, multi-sample, single-use 'butterfly' style blood collection set intended to be used by trained healthcare professionals for venipuncture to obtain blood specimens from patients into blood collection tubes or blood culture bottles. When used without the male adapter, the device allows the clinician to obtain a blood specimen from the female hub with a syringe. | Both devices are sterile, multi-sample, single-use 'winged' ('butterfly' style named so due to wing features) blood collection sets.<br><br>Both devices are indicated for use by trained healthcare professionals for venipuncture and blood collection into blood collection tubes and/or blood collection bottles.<br><br>Both devices are indicated for use without the male adapter to allow a clinician to obtain a blood specimen from the female hub with a syringe. |

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| | infusions with consideration given to patient size and<br>appropriateness for the solution being infused. The device is not to be left in place and is to remain under the<br>direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury. | | The predicate device is indicated for use for short-term single IV infusions, the subject device is not indicated for use for short term IV infusions, this has no effect on its safety or effectiveness as a blood collection set; the device box and IFU are marked with the warning: “This device is not indicated for short-term infusions”. |
| Used for short term IV infusion | Yes | No | Short term IV infusion is not being indicated for Unistik ShieldLock, this has no effect on its safety or effectiveness as a blood collection set; the device box and IFU are marked with the warning: “This device is not indicated for short-term infusions”. |
| Frequency of Use | As required by healthcare professional | As required by healthcare professional | Same |
| Needle Gauges | 21G, 23G, 25G | 20G, 21G, 22G, 23G, 25G | Additional gauges of 20G and 22G. 22G is within the range of the predicate, so no effect on safety/effectiveness.<br>Some patients may require a different gauge lancet to achieve the required blood flow. Therefore, the addition of the 20G needle variant represents a slightly larger outer diameter needle than seen in the predicate. 20G needles are widely used in healthcare and selected as necessary by the healthcare professional to meet patient needs. There is no additional risk or effect on safety and effectiveness associated with differential needle |

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| | | | gauges, and these do not affect depth of penetration.<br>To confirm safety and effectiveness, the devices have been tested to ISO 7864:2016, ISO 9626:2016 and are confirmed to meet the required specifications. |
| Needle length | ¾ inch | ¾ Inch | Same |
| Tube lengths | 178mm, 305mm | 200mm, 300mm | Subject device lengths are similar to the predicate, and within the range of the predicate, so no effect on safety/effectiveness. |
| Pre-attached blood tube holder? | Available with or without pre-attached “BD Vacutainer One Use Holder” | Available with or without pre-attached Unistik Holder | Same<br>Both devices are available with or without pre-attached holder, and both devices have holders available to purchase separately. |
| Luer Lock Adapter | Yes | Yes | Same |
| Integral sharps injury prevention feature? | Yes | Yes | Both have a sharps injury protection feature, differences discussed in this table below. |

| | | | |
|---|---|---|---|
| Sharps injury prevention safety feature operating principle? | Safety feature is designed to be activated while needle is still in the patient’s vein.<br>Gauze pad is placed across the venipuncture site, covering the front barrel. While the needle is still in the vein, the device body is grasped with the thumb and middle finger.<br>The push button is activated with the tip of the index finger causing the needle to retract into the device body. | Safety feature is activated after the needle is removed from the patient’s vein.<br>One-handed procedure: Hold the end of the safety shield with your thumb and index finger and use the remaining fingers to hold the tubing securely in the palm of your hands. Push the safety shield towards the needle until an audible click is heard.<br>Two-handed procedure: Hold the end of the safety shield with your thumb and index finger in one hand, with the other hand, pull the | Both devices have a safety feature that can be activated by one hand using the thumb/index finger.<br>The predicate device safety feature is activated while still in the patient vein, whereas the subject device safety feature is activated once removed from the patient vein. The subject device safety feature can however be activated immediately after removal from the |

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|---|---|---|---|
| | | tubing backwards until an audible click is heard. | patient vein, resulting in very limited time with an exposed needle, reducing the risk of needle stick injury.<br><br>The subject device has an additional two-handed procedure listed for activation of the safety feature, wherein the tubing can be pulled with the second hand, removing the need to activate the safety feature with the thumb or finger.<br><br>The subject device differs in that the user is advised in the IFU to activate the safety feature until an audible 'click' is heard, confirming to the user that the safety feature has been activated.<br><br>The safety feature of both devices securely sheaths the needle behind a layer of solid plastic which forms a physical barrier between the patient/user and the exposed needle.<br><br>Safety feature testing was conducted in line with ISO 23908:2011 to confirm safety and effectiveness of the subject device; this was conducted on samples that were accelerated aged to the 5 year shelf life. |
| Single-use? | Yes | Yes | Same |
| Sterility | Sterile | Sterile | Same |
| Sterility Assurance Level (SAL) 10-6 | Yes | Yes | Same |

| | | | |
|---|---|---|---|
| Sterilization method | Gamma | Ethylene oxide | Different; sterilization method was validated per over kill method as qualified in accordance with Annex B of ISO 11135-1:2014 and been verified to the required SAL of $10^{-6}$; no effect on device safety/effectiveness. |
| Shelf Life | 2 Years | 5 Years | Different; the subject device has a shelf life of 5 years.<br>To confirm the safety and effectiveness of the subject device, samples were sterilized, accelerated aged to 5 years and then tested in accordance with the following standards:<br>ISO7864:2016<br>ISO9626-2016<br>ISO 80369-7:2016<br>ISO 80369-20:2015<br>ISO 23908: 2011<br>Package integrity testing in accordance with:<br>ASTM F88/F88M-15<br>ASTM F 1929-15<br>ASTM F1886 / F1886M-16<br>Simulated Transportation Testing in accordance with ISTA 3A (2018) |
| Non-pyrogenic | Yes | Yes | Same |
| Non-toxic | Yes | Yes | Same |
| Materials | Compliant with ISO 10993 series | Compliant with ISO 10993 series | Same |
| Operating principle | Venipuncture performed by force generated by healthcare professional | Venipuncture performed by force generated by healthcare professional | Same |
| Needle Material | Stainless steel cannula | Stainless steel cannula | Same |
| Needle Point | 5 bevel | 3 bevel | Different, both represent industry standard, no |

<table>
<tr><td></td><td></td><td></td><td>impact on safety or effectiveness</td></tr>
<tr><td>Packaging</td><td>Shelf box – Cardboard Laminate<br>Individual Units – Blister Packed</td><td>Shelf box – Cardboard Laminate<br>Individual Units – Blister Packed</td><td>Same</td></tr>
<tr><td>Components and Materials</td><td>Stainless Steel, Silicone, UV Curing adhesive, Polyvinyl Chloride, Acrylonitrile butadiene styrene, Epoxy Resin, Isoprene Rubber, Polypropylene<br><br>Polyolefin, UV Curable Ink, Acrylic, Isopropyl Alcohol, Polyethylene<br><br>
<table>
<tr><td>Wing</td><td>Polyolefin</td></tr>
<tr><td>Hub</td><td>Polypropylene</td></tr>
<tr><td>Button Ink</td><td>UV Curable Ink</td></tr>
<tr><td>Front Barrel</td><td>Polypropylene</td></tr>
<tr><td>Rear Barrel</td><td>Acrylic</td></tr>
<tr><td>Rear Barrel Lubricant</td><td>Silicone</td></tr>
<tr><td>Rear Barrel Lubricant Diluent</td><td>Isopropyl Alcohol</td></tr>
<tr><td>Spring</td><td>Stainless Steel 302</td></tr>
<tr><td>IV Protector (Cannula Protector)</td><td>Polyethylene</td></tr>
<tr><td>IV Cannula/NP Cannula</td><td>Stainless Steel 304</td></tr>
<tr><td>Tubing</td><td>Polyvinyl Chloride</td></tr>
</table>
<br>
<table>
<tr><td>Cannula Lubricant</td><td>Silicone</td></tr>
<tr><td>Cannula Adhesive</td><td>UV cured adhesive</td></tr>
<tr><td>Hub-Tubing Adhesive</td><td>UV cured adhesive</td></tr>
</table></td><td>Stainless Steel, Silicone, UV Curing adhesive, Polyvinyl Chloride, Acrylonitrile butadiene styrene, Epoxy Resin, Isoprene Rubber, Polypropylene<br><br>
<table>
<tr><td>Needle tube</td><td>Stainless Steel 304</td></tr>
<tr><td>Lubricate</td><td>Silicone oil</td></tr>
<tr><td>Adhesive of patient-end needle</td><td>UV curing adhesive</td></tr>
<tr><td>Needle wing</td><td>Polyvinyl Chloride</td></tr>
<tr><td>Flexible tube</td><td>Polyvinyl Chloride</td></tr>
<tr><td>Needle hub (male luer lock connector)</td><td>Acrylonitrile butadiene</td></tr>
<tr><td>Connect base (female luer lock connector)</td><td>Acrylonitrile butadiene</td></tr>
<tr><td>Puncture needle</td><td>Stainless Steel 304</td></tr>
<tr><td>Adhesive of puncture needle</td><td>Epoxy Resin</td></tr>
<tr><td>Rubber sleeve</td><td>Isoprene Rubber</td></tr>
<tr><td>Needle Cap</td><td>Polyvinyl Chloride</td></tr>
</table></td><td>Same – all materials for subject device are used in the predicate device. The additional materials used in predicate are for components that are not included in the subject device. The subject device component/materials were tested in accordance to ISO10993 series and therefore the difference in components and materials do not raise new or different questions of safety and effectiveness.</td></tr>
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| | | | | | |
|---|---|---|---|---|---|
| | Female Luer Connectors | Acrylonitrile Butadiene Styrene | Safety Sheath | Polypropylene | |
| | Luer Adapter Hub | Polypropylene | | | |
| | NP Sleeve | Synthetic Isoprene Rubber | | | |
| | Luer Adhesive | Heat Curing Epoxy Resin | | | |
| | Luer Cannula Lubricant | Medical Grade Silicone | | | |
| | Luer Cap | Polypropylene | | | |
| | Top Web | Paper | | | |
| | Blister | Polyethylene terephthalate – glycol modified | | | |
| | Pre-attached holder | Polypropylene | | | |

*Table 5.3: Comparison of the technical characteristics between the subject device Unistik VacuFlip and the predicate device*

| Test/ Characteristic | BD Vacutainer® Eclipse™ Blood Collection Needle; (K982541) | Subject Device: Unistik® VacuFlip | Comparison |
|---|---|---|---|
| Patient Target Group | General use | General use | Same |
| Indications for Use Statement | The Vacutainer Brand ECLIPSE Blood Collection Needle is a sterile, multiple sample, single-use device for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needle sticks. | Unistik VacuFlip: The UniStik VacuFlip Safety Blood Collection Needle is intended to be used by healthcare professionals with vacuum blood collection tubes for multiple collections of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. | Both devices are sterile, multiple sample single use devices for blood collection.<br><br>Both devices are indicated for use by healthcare professionals.<br><br>Both devices feature a user activated safety shield that covers the needle to help protect against needle stick injury. |
| Frequency of Use | As required by healthcare professional | As required by healthcare professional | Same |
| Needle Gauges | 20G, 21G, 22G | 20G, 21G, 22G | Same<br><br>To confirm safety and effectiveness, the devices have been tested to ISO 7864:2016, ISO 9626:2016 and are confirmed to meet the required specifications. |
| Needle length | 1 ¼ inch | 1 inch, 1 ¼ inch, 1 ½ inch | Same |
| Integral sharps injury prevention feature? | Yes | Yes | Same |
| Safety feature activation method | User activates with thumb after venipuncture, shield ‘pivots’ around the hinge, locking into place at the needle base and at the cannula | User activates with thumb after venipuncture, shield ‘pivots’ around the hinge, locking into place at the needle base and at the cannula | Same |

| Test/ Characteristic | BD Vacutainer® Eclipse™ Blood Collection Needle; (K982541) | Subject Device: Unistik® VacuFlip | Comparison |
|---|---|---|---|
| Single-use? | Yes | Yes | Same |
| Sterility | Sterile | Sterile | Same |
| Sterility Assurance Level (SAL) 10-6 | Yes | Yes | Same |
| Sterilization method | Gamma | Ethylene oxide | Different; sterilization method was validated per over kill method as qualified in accordance with Annex B of ISO 11135-1:2014 and been verified to the required SAL of $10^{-6}$; no effect on device safety/effectiveness. |
| Shelf Life | 5 Years | 5 Years | Same |
| Yes | Yes | Same | Yes |
| Pre-attached blood tube holder? | Attached holder configuration available | Attached holder configuration available | Same |
| Non-pyrogenic | Yes | Yes | Same |
| Non-toxic | Yes | Yes | Same |
| Materials | Compliant with ISO 10993 series | Compliant with ISO 10993 series | Same |
| Operating principle | Venipuncture performed by force generated by healthcare professional | Venipuncture performed by force generated by healthcare professional | Same |
| Packaging | Shelf box – Cardboard Laminate<br>Individual Units – Blister Packed | Shelf box – Cardboard Laminate<br>Individual Units – Blister Packed | Same |
| Components and materials | Cannula- stainless steel<br>Hub- polystyrene<br>Safety Shield- polypropylene<br>Rubber Sleeve- synthetic rubber<br>Holder (integrated model)- polypropylene<br>Lubricant- silicone | Needle tube- Stainless Steel 304<br>Lubricant – Silicone oil<br>Adhesive of patient-end needle - UV cured adhesive<br>Needle hub (male luer lock connector) Polypropylene | Similar – both devices use Stainless steel, silicone, polypropylene.<br><br>The subject device uses isoprene rubber which is a form of synthetic rubber; the predicate just lists ‘synthetic rubber’. |

| Test/ Characteristic | BD Vacutainer® Eclipse™ Blood Collection Needle; (K982541) | Subject Device: Unistik® VacuFlip | Comparison |
|---|---|---|---|
| | | Connect base (female luer lock connector)- Acrylonitrile butadiene<br>Puncture needle – Stainless Steel 304<br>Adhesive of puncture needle- Epoxy Resin<br>Rubber sleeve- Isoprene Rubber<br>Needle cap- Polypropylene<br>Safety sheath- Polypropylene<br>Needle holder- Polypropylene | The subject device lists additionally: UV cured adhesive and Epoxy Resin.<br>The devices were functionally tested to confirm efficacy of these materials.<br>The patient contact materials were tested as required in accordance with:<br>ISO 10993-5:2009,<br>ISO 10993-10:2010,<br>ISO 10993-11:2017<br>ASTM F756-2017<br>ISO 10993-4:2017<br><br>All materials were found to meet specification. |

## 7. Performance Data

**Non-clinical performance data:**

Design verification testing has been performed on the Unistik® ShieldLock and Unistik VacuFlip lancets to demonstrate that the devices operate safely and effectively. Testing has been conducted to evaluate the performance of the devices against defined acceptance criteria.

**Bench Testing**

Performance testing (bench testing) was conducted on the subject devices and the results demonstrate that the subject devices operate safely and effectively as intended.

*Table 5.4 List of tests performed on Unistik® ShieldLock*

| Test | Requirement | Results |
|---|---|---|
| Cleanliness | ISO7864:2016 | Meets specification |
| Limits of Acidity or Alkalinity | ISO7864:2016 | Meets specification |
| Limits for Extractable Metals | ISO7864:2016 | Meets specification |
| Tubular Needle Designation Test | ISO7864:2016 | Meets specification |

| | | |
|---|---|---|
| Color Coding Test | ISO7864:2016 | Meets specification |
| Conical Fitting Test | ISO7864:2016 | Meets specification |
| Colour of Hub Test | ISO7864:2016 | Meets specification |
| Needle Cap Test | ISO7864:2016 | Meets specification |
| General-Needles and Tapered-Needles Test | ISO7864:2016 | Meets specification |
| Tolerances on Length Test | ISO7864:2016 | Meets specification |
| Freedom from Defects Test | ISO7864:2016 | Meets specification |
| Lubricant Test | ISO7864:2016 | Meets specification |
| Needle Point Test | ISO7864:2016 | Meets specification |
| Needle Retention Test | ISO7864:2016 | Meets specification |
| Patency of Lumen Test | ISO7864:2016 | Meets specification |
| Surface Finish and Visual Test | ISO9626:2016 | Meets specification |
| Cleanliness Test | ISO9626:2016 | Meets specification |
| Limits for Acidity & Alkalinity Test | ISO9626:2016 | Meets specification |
| Size Designation Test | ISO9626:2016 | Meets specification |
| Dimensions Test Record | ISO9626:2016 | Meets specification |
| Stiffness Test Records | ISO9626:2016 | Meets specification |
| Test Records for Resistance of Tubing to Breakage | ISO9626:2016 | Meets specification |
| Test Records for Resistance to Corrosion | ISO9626:2016 | Meets specification |
| Fluid Leakage Test | ISO80369-7:2016 | Meets specification |
| Subatmospheric Pressure Air Leakage | ISO80369-7:2016 | Meets specification |
| Stress Cracking Test | ISO80369-7:2016 | Meets specification |
| Resistance to separation from axial load | ISO80369-7:2016 | Meets specification |
| Safety Feature Testing | ISO 23908:2011 | Meets specification |

| | | |
|---|---|---|
| Particulate Matter Test | USP 788 | Meets specification |
| Package Integrity Testing | ASTM F88/F88M-15<br>ASTM F 1929-15<br>ASTM F1886 / F1886M-16 | Meets specification |
| Simulated Transportation Test | ISTA 3A (2018) | Meets specification |

*Table 5.5 List of tests performed on Unistik® VacuFlip*

| Test | Requirement | Results |
|---|---|---|
| Cleanliness | ISO7864:2016 | Meets specification |
| Limits of Acidity or Alkalinity | ISO7864:2016 | Meets specification |
| Limits for Extractable Metals | ISO7864:2016 | Meets specification |
| Tubular Needle Designation Test | ISO7864:2016 | Meets specification |
| Color Coding Test | ISO7864:2016 | Meets specification |
| Conical Fitting Test | ISO7864:2016 | Meets specification |
| Colour of Hub Test | ISO7864:2016 | Meets specification |
| Needle Cap Test | ISO7864:2016 | Meets specification |
| General-Needles and Tapered-Needles Test | ISO7864:2016 | Meets specification |
| Tolerances on Length Test | ISO7864:2016 | Meets specification |
| Freedom from Defects Test | ISO7864:2016 | Meets specification |
| Lubricant Test | ISO7864:2016 | Meets specification |
| Needle Point Test | ISO7864:2016 | Meets specification |
| Needle Retention Test | ISO7864:2016 | Meets specification |
| Patency of Lumen Test | ISO7864:2016 | Meets specification |
| Surface Finish and Visual Test | ISO9626:2016 | Meets specification |
| Cleanliness Test | ISO9626:2016 | Meets specification |
| Limits for Acidity & Alkalinity Test | ISO9626:2016 | Meets specification |
| Size Designation Test | ISO9626:2016 | Meets specification |
| Dimensions Test Record | ISO9626:2016 | Meets specification |
| Stiffness Test Records | ISO9626:2016 | Meets specification |
| Test Records for Resistance of Tubing to Breakage | ISO9626:2016 | Meets specification |
| Test Records for Resistance to Corrosion | ISO9626:2016 | Meets specification |
| Fluid Leakage Test | ISO80369-7:2016 | Meets specification |

| | | |
|---|---|---|
| Subatmospheric Pressure Air Leakage | ISO80369-7:2016 | Meets specification |
| Stress Cracking Test | ISO80369-7:2016 | Meets specification |
| Resistance to separation from axial load | ISO80369-7:2016 | Meets specification |
| Safety Feature Testing | ISO 23908:2011 | Meets specification |
| Particulate Matter Test | USP 788 | Meets specification |
| Package Integrity Testing | ASTM F88/F88M-15<br>ASTM F 1929-15<br>ASTM F1886 / F1886M-16 | Meets specification |
| Simulated Transportation Test | ISTA 3A (2018) | Meets specification |

The subject 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® ShieldLock and Unistik VacuFlip are safe and effective when used as intended.

**Biocompatibility:**

In accordance with ISO 10993-1:2018, the Unistik® ShieldLock and Unistik VacuFlip devices are classified as shown in Table 5.6 below.

*Table 5.6 - ISO 10993-1:2018 classification of Unistik® SheildLock & VacuFlip*

| | |
|---|---|
| Category | Externally communicating device |
| Contact | Circulating blood |
| Contact duration | A (Limited; ≤ 24 hours) |

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.

The following Biocompatibility standards were used when assessing the biocompatibility of the subject devices:

ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
ASTM F756-2017 Standard Practice for Assessment of Hemolytic Properties of Materials.
ISO 10993-4:2017 Biological Evaluation of Medical Devices Part 4: Selection of tests for

interactions with blood

**Sterilization:**

The Unistik® ShieldLock Blood Collection Set & Unistik VacuFlip Blood Collection Needle are supplied to the user in a sterile state and remain sterile for 5 years from the date of sterilization. The devices are single-use and are not intended to be reprocessed and re-used. The Unistik® ShieldLock Blood Collection Set & Unistik VacuFlip Blood Collection Needle are sterilized by ethylene oxide sterilization in Accordance with ISO 11135-1:2014. The sterilization cycle below was validated per over kill method as qualified in accordance with Annex B of ISO 11135-1:2014 – "*Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release".*

The following standards were used to assess the sterility and shelf life of the device:

ISO 11135-1:2014 – "Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release"
ISO 10993-7:2008 - Biological evaluation of medical devices
Simulated Transportation Test: ISTA 3A (2018)
ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials (Sterility)
ASTM F 1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration
ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

## 8. Clinical Testing

No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device

## 9. Conclusion

It can be concluded that the differences between the subject devices, Unistik® ShieldLock Blood Collection set and Unistik® VacuFlip and predicate devices do not raise any new or different questions of safety or effectiveness. The subject device is substantially equivalent to the predicate devices, BD Vacutainer® UltraTouch™ Push Button Blood Collection Set, cleared under K212724 and BD Vacutainer® Eclipse™ Blood Collection Needle, cleared under K982541.