August 29, 2022

SB-Kawasumi Laboratories, Inc.
% Valerie Followell
Official Correspondent for Kawasumi Laboratories, Inc. / Regulatory Consultant
Regulatory Compliance Associates, Inc. (RCA)
10411 Corporate Drive, Suite 102
Pleasant Prairie, Wisconsin 53158

Re: K220799
Trade/Device Name: K-SHIELD Zen
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FMI
Dated: July 29, 2022
Received: August 1, 2022

Dear Valerie Followell:

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,

David Wolloscheck, Ph.D.
For Payal Patel
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K220799

Device Name
K-SHIELD Zen

Indications for Use *(Describe)*
K-SHIELD Zen is designed for accessing peripheral veins to collect blood. The Press Button anti-needle stick protector is an integral safety device intended to minimize accidental needlestick injuries.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# K220799 510(k) Summary

## I. SUBMITTER

### *Sponsor/Manufacturer*

SB-KAWASUMI LABORATORIES, INC.
3-25-4 Tonomachi,
Kawasaki-ku, Kawasaki-shi,
Kanagawa 210-8602, Japan
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### *US Contact and Official Correspondent for SB-KAWASUMI LABORATORIES, INC.*

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## II. DEVICE

| | |
|---|---|
| *Device Trade/Proprietary Name:* | **K-SHIELD Zen** |
| *Device Common or Usual Name:* | Blood Specimen Collection Device |
| *Device Classification Name:* | Tubes, Vials, Systems, Serum Separators, Blood Collection |
| *Device Regulatory Classification:* | Class II |
| *Device Classification Regulation:* | 21 CFR 862.1675 |
| *Product Code:* | JKA – Blood Specimen Collection Device<br>FMI – Needle, Hypodermic, Single Lumen |
| *Submission Type:* | 510(k) |
| *Classification Panel:* | General Hospital |

## III. PREDICATE DEVICE

| | |
|---|---|
| *Predicate Device:* | • **BD VACUTAINER Push Button Blood Collection Set (K011984)** |

## IV. DEVICE DESCRIPTION

The K-SHIELD Zen is a winged blood collection set consisting with a cannula, flexible tube, connection parts and the Press Button anti-needle stick protector designed to minimize accidental needlestick injuries when accessing peripheral veins to collect patient blood. The Press Button anti-needle stick protector stores the needle within the housing when the activation button is pressed after blood collection procedure.
This product has a variety of Needle gauge sizes (21G, 23G, 25G) and a lineup of 3 types of connection parts, Luer connector (PBM), Multiple Sample Luer Adapter (PBMA) and Pre-attached Holder (PBMH). During blood collection, the Luer connector is connected to a syringe. Multiple Sample Luer Adapter and Pre-attached holder are connected to vacuum blood collection tubes / blood culture bottles to obtain multiple samples. The different configurations (connection options) are chosen by the user based on facility blood collection procedure.
The mechanism of action for the device, all configurations, is blood collection using syringes or vacuum blood collection tubes / blood culture bottles to assist the user with obtaining blood from a patient.
The device is intended for the Adult population only. Do not use in pediatric age groups, including newborn, neonate, or children.

The K-SHIELD Zen is a single use, disposable Ethylene Oxide Sterilized medical device. Sterilization Validation was conducted per *ISO 11135: 2014 – Sterilization of Health-Care Products – Ethylene Oxide –Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*.

The K-SHIELD Zen is considered blood path, indirect, limited contact (< 24 hours) per *ISO 10993-1: 2018 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.* All device materials comply with ISO 10993-1.

The K-SHIELD Zen is a sterile, single-use device that consists of the following components:

- Winged needle with Press Button Anti-needle Stick Protector
- Main Tube
- Clip
- Connector Tube
- Luer Connector
- Locking Cap (optional)
- Multiple Sample Luer Adapter (optional)
- Pre-attached Holder (optional)

The K-SHIELD Zen is intended for use at healthcare facilities or in hospitals.

**V. INTENDED USE**

K-SHIELD Zen is designed for accessing peripheral veins to collect blood. The Press Button anti-needle stick protector is an integral safety device intended to minimize accidental needlestick injuries.

**VI. INDICATIONS FOR USE**

K-SHIELD Zen is designed for accessing peripheral veins to collect blood. The Press Button anti-needle stick protector is an integral safety device intended to minimize accidental needlestick injuries.

**VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The comparison of the similarities and differences between the K-SHIELD Zen (subject device) and the BD VACUTAINER Push Button Blood Collection Set (K011984) (predicate device) is provided in the Substantial Equivalence (SE) Comparison Table below.

| **Substantial Equivalence (SE) Comparison Table** | | | |
|---|---|---|---|
| | **K-SHIELD Zen (Subject Device)** | **BD VACUTAINER Push Button Blood Collection Set (K011984) (Predicate Device)** | **Same/Similarities/ Differences** |
| *Manufacturer* | SB-KAWASUMI LABORATORIES, INC | Becton Dickinson | -- |
| *Device Trade or Proprietary Name* | K-SHIELD Zen | BD VACUTAINER Push Button Blood Collection Set | -- |
| *510(k) Number* | K220799 | K011984 | -- |
| *Device Class* | Class II | Class II | Same |
| *Product Code* | JKA and FMI | FMI and JKA | Same |
| *Regulation Number* | 21 CFR 862.1675 | 21 CFR 880.5570<br>21 CFR 862.1675 | Same |
| *Indications for Use* | K-SHIELD Zen is designed for accessing peripheral veins to collect blood. The Press Button anti-needle stick protector is an integral safety device intended to minimize | The BD VACUTAINER Push Button Blood Collection Set is a sterile, multiple-sample, single-use winged blood collection set intended for venipuncture to obtain blood | Different. The difference in wording of Indications for use does not raise any new or different questions of safety and effectiveness. |

| | | | |
|---|---|---|---|
| | accidental needlestick injuries. | specimens from patients. The recommended use of the device is to activate the needle prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of needlestick injury. | |
| *Device Description* | The K-SHIELD Zen is a sterile, single use winged blood collection set consisting with cannula, flexible tube, connection parts and the Press Button anti-needle stick protector designed to minimize accidental needlestick injuries when accessing peripheral veins to collect patient blood. The Press Button anti-needle stick protector stores the needle within the housing when the activation button is pressed after blood collection procedure. | The BD VACUTAINER Push Button Blood Collection Set is for venous blood collection. The wing set contains a needle that will retract into the body of the device when a button is depressed, helping to prevent accidental needle sticks. The retraction of the needle occurs when the user depresses the button. | Same |
| *Press Button Feature* | Yes | Yes | Same |
| *Anti-Needle Stick Prevention* | Yes | Yes | Same |
| *Color-Coded Wing* | Yes | Yes | Same |
| *Needle* | Stainless Steel | Stainless Steel | Same |
| *Needle Gauge Diameter OD* | 21G, 23G, 25G | 21G, 23G, 25G | Same |
| *Needle Diameter ID* | Ultra-Thin Wall | Thin Wall | Different. The difference in the diameter does not raise new or different questions of safety and effectiveness. Performance Testing was |

| | | | |
|---|---|---|---|
| | | | conducted to demonstrate substantial equivalence. |
| *Needle Protector* | PP | Information not available | Different (assumed). Subject device materials comply with ISO 10993-1 and have a long history of use in medical device applications. |
| *Needle Sheath Cover* | Isoprene Rubber | Isoprene Rubber | Same |
| *Wing* | PP | Polyolefin | Different. The different but comparable material of the wing does not raise new or different questions of safety and effectiveness. Both materials comply with ISO 10993-1 and have a long history of use in medical device applications. Non-Clinical Testing was conducted to demonstrate SE. |
| *Tubing* | PVC | PVC | Same |
| *Female Luer Connector* | ABS | ABS | Same |
| *Luer Adaptor Hub* | PP | PP | Same |
| *Adhesive* | Heat Curing Epoxy | Heat Curing Epoxy | Same |

| | | | |
|---|---|---|---|
| *Packaging* | Envelope Pouch | Blister Pack | Different. The different but comparable packaging does not raise new or different questions of safety and effectiveness. Non-Clinical Testing was conducted to demonstrate SE. |
| *Materials Comply with ISO 10993-1* | Materials comply with ISO 10993-1 | Materials comply with ISO 10993-1 | Same |
| *Non-Pyrogenic* | Non-Pyrogenic | Non-Pyrogenic | Same |
| *Non-Toxic* | Non-Toxic | Non-Toxic | Same |
| *Prescription (Rx) or Over- the Counter (OTC) Use* | Prescription Use | Prescription Use | Same |
| *Use Environment* | Hospital / Clinic | Hospital / Clinic | Same |
| *Single-Use* | Single-Use Only | Single-Use Only | Same |
| *Sterile* | Sterile | Sterile | Same |
| *Sterility Assurance Level (SAL $10^{-6}$)* | SAL $10^{-6}$ | SAL $10^{-6}$ | Same |
| *Sterilization Method* | Ethylene Oxide Sterilization (EtO) | Gamma Radiation | Different. The difference in sterilization method does not raise new or different questions of safety and effectiveness. Product Sterility Testing was conducted to demonstrate SE. |

| | | | |
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| *Shelf-Life* | 3 Year Shelf-Life | 2 Year Shelf-Life | Different. The difference in Shelf-Life does not raise new or different questions of safety and effectiveness. Shelf- Life Testing was conducted to demonstrate SE. |

## VIII. SUMMARY OF PERFORMANCE DATA AND PERFORMANCE TEST CONCLUSIONS

The following Performance Data were provided in support of the substantial equivalence (SE) determination.

| ***Summary of Non-Clinical Bench Performance Testing*** |
|---|
| Non-Clinical Bench Performance Testing was conducted on the K-SHIELD Zen [subject device]. The table below includes the list of the performance testing results submitted, referenced, or relied on in this premarket notification submission for a determination of substantial equivalence. |

| **Biocompatibility Testing** | |
|---|---|
| **<u>Biocompatibility Testing</u>** including:<br>• Cytotoxicity<br>• Sensitization<br>• Intracutaneous Reactivity<br>• Systemic Toxicity<br>• Hemocompatibility<br>• Pyrogenicity<br>• In Vitro Partial Thromboplastin Time (PTT) Test<br>• In Vitro Hemocompatibility Assessment by Evaluating Platelet Leukocyte Counts and its Adherence Testing<br>***<u>FDA Recognized Testing Standards:</u>***<br>• *ISO 10993-1:2018-Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*<br>• *ISO 10993-4:2017-Biological Evaluation of Medical Devices - Part 4: Selections of Tests for Interactions with Blood*<br>• ISO 10993-5:2009-*Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity*<br>• ISO 10993-10:2010-*Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*<br>• ISO 10993-11:2017-*Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity*<br>• *ASTM F756-17-Standard Practice for Assessment of Hemolytic Properties of Materials*<br>• *ASTM F2382-18 - Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)*<br>• *ASTM F2888-19 – Standard Practice for Platelet Leukocyte Count-An In-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Material*<br>• *USP General Chapter<151> Pyrogen Test (USP Rabbit Test), USP42-NF37* | ***<u>Test Results:</u>* PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination. |
| **Simulated Use Testing** | |
| **<u>Simulated Use Testing</u>**<br>**<u>FDA Recognized Standards</u>**<br>• *ISO 23908:2011: Sharps Injury Protection-Requirements and Test Methods-Sharps Protection Features for Single-Use Hypodermic Needles, Introducers for Catheters, and Needles used for Blood Sampling*<br>• *FDA Guidance document – Medical Devices with Sharps Injury Prevention Features, CDRH issued, 2005* | ***<u>Test Results:</u>* PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination. |

<table>
<tr><th colspan="2">Particulate Contamination Testing</th></tr>
<tr><td><u>Particulate Contamination Testing</u><br><br><u>FDA Recognized Testing Standards:</u><br>• USP General Chapter <788> Particulate Matter in Injections, USP42-NF37</td><td><u>Test Results</u>: PASSED<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination.</td></tr>
<tr><th colspan="2">Functional Testing / Packaging Study/ Physical Testing<br>(Including Stability Testing)</th></tr>
<tr><td><u>Functional Testing</u> including:<br>• False Sting Prevention Operation Check<br>• Piercing Resistance Test<br><u>Packaging Study</u> including:<br>• Transportation<br>• Packaging<br>▪ Appearance<br>▪ Seal Strength<br>▪ Dye Test<br>▪ Bubble Test<br>▪ Stability test<br><u>Physical Testing (Including Stability Testing)</u> including:<br>• Leakage<br>• Tensile Strength<br>• Bonding Strength<br>• Blood-Taking Needle<br>• Tolerance on Length<br>• Needle Point<br><u>FDA Recognized Testing Standards:</u><br>• ISO 1135-3:2016 (Second Edition 2016-11) - Transfusion Equipment for Medical Use – Part 3: Blood-Taking Sets for Single-Use<br>• ISO 7864:2016 (Fourth Edition 2016-08-01) - Sterile Hypodermic Needles for Single-Use: Requirements and Test Methods<br>• ISO 11607-1:2019 (E): Packaging for terminally sterilized medical devices-Part I: Requirements for materials, sterile barrier systems and packaging systems<br>• ISO 11607-2:2019 (E): Packaging for terminally sterilized medical devices-Part 2: Validation Requirements for Forming, Sealing and Assembly process<br>• ASTM D4169-16: Standard Practice for Performance Testing of Shipping Containers and Systems<br>• ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)</td><td><u>Test Results</u>: PASSED<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination.</td></tr>
</table>

| Needle Cover Strength Testing | |
|---|---|
| **Needle Cover Strength Testing**<br><br>**In-House Testing Methods/Standards Utilized for:**<br>• Needle Cover Strength Testing | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data demonstrate that the needle cover strength met the applicable In-House Testing Method/Standard utilized for this device specific testing which is required per the FDA Guidance on the Content of Premarket Notification [510(k)] Submissions for Hypodermic Single Lumen Needles. Therefore, these results were provided in support of the substantial equivalence determination. |
| **ISO 9626:2016 Confirmation Testing** | |
| **ISO 9626:2016 Testing** including:<br>• Limits for acidity and alkalinity<br>• Stiffness test<br>• Resistance to breakage<br>• Resistance to corrosion<br><br>**FDA Recognized Standards**<br>• *ISO 9626:2016: Stainless Steel Needle Tubing for the Manufacture of Medical Devices-Requirements and Test Methods* | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination. |

| ISO 7864:2016 Patency of Lumen Testing | |
|---|---|
| **ISO 7864:2016 Testing** including:<br>• Patency of Lumen<br>**FDA Recognized Standards**<br>• *ISO 7864:2016: Sterile Hypodermic Needles for Single Use-Requirements and Test Methods* | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination. |
| **ISO 23908:2011 Confirmation Testing** | |
| **ISO 23908:2011 Testing** including:<br>• ISO 23908 Confirmation Test (Sphere Simulation)<br>• ISO 23908 Confirmation Test (Testing Simulated Clinical Use)<br>• ISO 23908 Confirmation Test (Challenging the Device in Safe Mode)<br>• ISO 23908 Confirmation Test (Testing Activation of a Sharps Injury Protection Feature)<br>**FDA Recognized Standards**<br>• *ISO 23908:2011: Sharps Injury Protection-Requirements and Test Methods-Sharps Protection Features for Single-Use Hypodermic Needles, Introducers for Catheters, and Needles used for Blood Sampling* | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination. |
| **ISO 80369-7:2016 Compliance Testing** | |
| **ISO 80369-7:2016 Testing** including:<br>• ISO 80369-7:2016 Compliance Test, Identification of ISO 80369-7 in Luer Connector (Accelerated 0 Month/6 Months/3 Years)<br>**FDA Recognized Standards**<br>• *ISO 80369-7:2016: Small-Bore Connectors for Liquids and Gases in Healthcare Applications-Part 7: Connectors for Intravascular or Hypodermic Applications* | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination. |

<table>
<tr><th colspan="2">Chemical Testing (Including Stability Testing)</th></tr>
<tr><td><u>Chemical Testing (Including Stability Testing)</u><br>• Reducing Oxidizable Matter<br>• Metal Ions<br>• Titration Acidity or Alkalinity<br>• Residue on Evaporation<br>• UV Absorption of Extract Solution (UV)<br>• EtO Residuals<br><u>FDA Recognized Testing Standards:</u><br>• ISO 10993-7:2008 (Second Edition 2008-10-15) – Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals<br>• ISO 1135-3:2016 (Second Edition 2016-11) - Transfusion Equipment for Medical Use – Part 3: Blood-Taking Sets for Single-Use</td><td><u>Test Results</u>: PASSED<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination.</td></tr>
<tr><th colspan="2">Sterility Testing</th></tr>
<tr><td><u>Sterility Testing</u><br><br><u>FDA Recognized Testing Standards:</u><br>• USP General Chapter <71> Sterility Test, USP 43, NF-38</td><td><u>Test Results</u>: PASSED<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination.</td></tr>
<tr><td colspan="2"><u>Conclusions</u>: The data generated from the results of the Non-Clinical Performance Bench Testing support the safety of the device and demonstrate that the K-SHIELD Zen performs as intended in the specified use conditions and comparably in terms of safety, effectiveness, and performance to the BD VACUTAINER Push Button Collection Set (K011984) [predicate device] which is currently marketed for the same intended use. Therefore, this Non-Clinical Performance Bench Testing supports a determination of substantial equivalence of the K-SHIELD Zen [subject device] when compared to the predicate device.</td></tr>
</table>

## IX. <u>OVERALL CONCLUSIONS</u>

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The K-SHIELD Zen is substantially equivalent to the BD VACUTAINER Push Button Blood Collection Set (K011984) with respect to indications for use, treatment method and technological characteristics.