June 1, 2023

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

Re: K230408
Trade/Device Name: K-SHIELD Zen (Model Numbers: PBMH/ PBMA/ PBM)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: May 2, 2023
Received: May 3, 2023

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.
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)*
K230408

Device Name
K-SHIELD Zen (Model Numbers: PBMH/ PBMA/ PBM)

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.

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510(k) Summary -K230408

DATE: 06/01/2023

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.

Valerie Followell

Official Correspondent

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Email: v.followell@rcainc.com

II. DEVICE

Device Trade/Proprietary Name:	**K-SHIELD Zen (Model Numbers: PBMH/ PBMA/ PBM)**
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 FMI – Needle, Hypodermic, Single Lumen
Submission Type:	510(k)
Classification Panel:	General Hospital

III. PREDICATE DEVICE

Predicate Device:	• **K-SHIELD Zen (K220799)**

IV. DEVICE DESCRIPTION

The K-SHIELD Zen is a sterile, single use 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 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 K-SHIELD Zen (K220799) (predicate device) is provided in the Substantial Equivalence (SE) Comparison Table below.

Substantial Equivalence (SE) Comparison Table			
	K-SHIELD Zen (Subject Device)	**K-SHIELD Zen (K220799) (Predicate Device)**	**Same/Similarities/ Differences**
Manufacturer	SB-KAWASUMI LABORATORIES, INC	SB-KAWASUMI LABORATORIES, INC	--
Device Trade or Proprietary Name	K-SHIELD Zen	K-SHIELD Zen	--
510(k) Number	K230408	K220799	--
Device Class	Class II	Class II	Same
Device Classification Name	Tubes, Vials, Systems, Serum Separators, Blood Collection	Tubes, Vials, Systems, Serum Separators, Blood Collection	Same
Device Common Name	Blood specimen collection device	Blood specimen collection device	Same
Product Code	JKA and FMI	JKA and FMI	Same

Regulation Number	21 CFR 862.1675	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 accidental needlestick injuries.	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.	Same
Intended Use	Same as Indications for Use	Same as Indications for Use	Same
Patient Population	Adults and Pediatric	Adults Only	Different (Biocompatibility assessments (DEHP extraction testing and risk assessment supports comparison)
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 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.	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	Ultra-Thin Wall	Same
Needle Protector	PP	PP	Same
Needle Sheath Cover	Isoprene Rubber	Isoprene Rubber	Same
Wing	PP	PP	Same
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	Envelope Pouch	Same
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)	Ethylene Oxide Sterilization (EtO)	Same

Shelf-Life	3 Year Shelf-Life	3 Year Shelf-Life	Same

VIII. SUMMARY OF PERFORMANCE DATA AND PERFORMANCE TEST CONCLUSIONS

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

<table>
<tr><th colspan="2">Summary of Non-Clinical Bench Performance Testing</th></tr>
<tr><td colspan="2">This submission is for the same device but for an expanded patient population and non-clinical performance and biocompatibility data is leveraged/referenced from K220799.

The table below includes the list of the testing results submitted specific to supporting this expanded patient population.</td></tr>
<tr><th colspan="2">Biocompatibility Testing</th></tr>
<tr><td><u>Biocompatibility Testing</u> including:
DEHP Extraction test
Risk Analysis Report of DEHP Exposure
<u>FDA Recognized Testing Standards:</u>
ISO 10993-17:2002(First Edition 2002-12-01) – Biological Evaluation of Medical Devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020 (Second edition 2020-01 Amendment 1 2022-05) - Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process [Including Amendment 1 (2022)]</td><td><u>Test Results:</u> PASSED
The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination.</td></tr>
<tr><th colspan="2">Chemical Testing</th></tr>
<tr><td><u>Chemical Testing</u>
EtO Residuals
<u>FDA Recognized Testing Standards:</u>
ISO 10993-7:2008 (Second Edition 2008-10-15) – Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]</td><td><u>Test Results:</u> PASSED
The result of the Non-Clinical Bench Performance Data was provided in support of the substantial equivalence determination.</td></tr>
</table>

IX. OVERALL CONCLUSIONS

- The K-SHIELD Zen [subject device] is substantially equivalent to the K-SHIELD Zen (K220799) [predicate device] with respect to indications for use, treatment method and technological characteristics.