November 26, 2025

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

Re: K252355
Trade/Device Name: K-SHIELD Advantage PORT ACCESS INFUSION SET With High Pressure Tubing
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: PTI, FPA
Dated: October 28, 2025
Received: October 28, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252355

Device Name
K-SHIELD Advantage PORT ACCESS INFUSION SET With High Pressure Tubing

Indications for Use *(Describe)*
This device is an intravascular administration set with a non-coring Huber needle used for drug administration and blood sampling through implanted vascular port systems.
The needle tip is equipped with an anti-needle stick protector to reduce the possibility of accidental needle sticks. This device is also applicable to high-pressure injection with power injectors, when used with a port system indicated for high-pressure injection.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K252355 - 510(k) Summary

## I. SUBMITTER

### *Sponsor/Manufacturer*

SB-KAWASUMI LABORATORIES, INC.
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Date Prepared: November 26, 2025

### *US Contact and Official Correspondent for SB-KAWASUMI LABORATORIES, INC.*

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## II. DEVICE

| | |
|---|---|
| *Device Trade/Proprietary Name:* | **K-SHIELD Advantage PORT ACCESS INFUSION SET With High Pressure Tubing** |
| *Device Common or Usual Name:* | Non-coring (Huber) needle |
| *Device Classification Name:* | Hypodermic single lumen needle. |
| *Device Regulatory Classification:* | Class II |
| *Device Classification Regulation:* | 21 CFR 880.5570 |
| *Product Code:* | PTI |
| *Secondary Product Code:* | FPA |
| *Submission Type:* | 510(k) |
| *Classification Panel:* | General Hospital |

## III. PREDICATE DEVICE

| | |
|---|---|
| *Predicate Device:* | PowerLoc Safety Infusion Set **(K060812)** |

## IV. DEVICE DESCRIPTION

The K-SHIELD Advantage PORT ACCESS INFUSION SET With High Pressure Tubing (here in after K-SHIELD Advantage HP-PAIS) is an intravascular administration set with a non-coring Huber needle used for drug administration and blood sampling through implanted vascular port systems.

The needle tip is equipped with an anti-needle stick protector to reduce the possibility of accidental needle sticks. This device is also applicable to high-pressure injection with power injectors, when used with a port system indicated for high-pressure injection.

This device has a Huber needle for insertion into the septum of an implanted port, for infusion and blood sampling through the port. This needle is equipped with wings of a specific shape and rigidity to ensure that the user can securely hold the device during needle insertion and withdrawal. Additionally, the alignment of the gripping position and the puncture point along a straight line supports accurate puncture placement. The device features a safety mechanism that activates upon needle withdrawal, with a safety shield covering the needle tip.

The activation of the safety mechanism is audibly confirmed by a click sound. Moreover, the device is equipped with high-pressure resistant tubing and clamp, enabling the supply of medications such as contrast media using an automatic injector.

Specification

| Needle gauge | Needle length | Tube length (mm) | |
|---|---|---|---|
| 19G | 3/4" | w/o Y site | 170 |
| | | With Y site | 100/100 |
| | 1" | w/o Y site | 170 |
| | | With Y site | 100/100 |
| 20G | 3/4" | w/o Y site | 170 |
| | | With Y site | 100/100 |
| | 1" | w/o Y site | 170 |
| | | With Y site | 100/100 |
| 22G | 3/4" | w/o Y site | 170 |
| | | With Y site | 100/100 |
| | 1" | w/o Y site | 170 |
| | | With Y site | 100/100 |

## V. INTENDED USE

This device is an intravascular administration set with a non-coring Huber needle used for drug

administration and blood sampling through implanted vascular port systems.

## VI. INDICATIONS FOR USE

This device is an intravascular administration set with a non-coring Huber needle used for drug administration and blood sampling through implanted vascular port systems. The needle tip is equipped with an anti-needle stick protector to reduce the possibility of accidental needle sticks. This device is also applicable to high-pressure injection with power injectors, when used with a port system indicated for high-pressure injection.

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

Comparison with the primary predicate device with similarities and differences noted.

| Features | Subject Device | Primary Predicate Device | Comparison |
|---|---|---|---|
| Device Name | K-SHIELD Advantage PORT ACCESS INFUSION SET With High Pressure Tubing | PowerLoc Safety Infusion Set | - |
| Intended Use | This device is an intravascular administration set with a non-coring Huber needle used for drug administration and blood sampling through implanted vascular port systems. | The PowerLoc SIS is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports. | Same (*1) |
| Indications for Use | This device is an intravascular administration set with a non-coring Huber needle used for drug administration and blood sampling through implanted vascular port systems.<br>The needle tip is equipped with an anti-needle stick protector to reduce the possibility of accidental needle sticks. This device is also applicable to high-pressure injection with power injectors, when used with a port system indicated for high-pressure injection. | The PowerLoc Safety Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle-stick safety mechanism. The device is used to access surgically implanted vascular ports.<br>The PowerLoc Safety Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports. When used with the PowerPort device, the PowerLoc Safety Infusion Set is also indicated for power injection of contrast media into the central venous system only with an implanted port that is also indicated for power injection. The maximum recommended infusion rate is 5 ml/s for 19 Ga. and 20 Ga. needles, and 2 ml/s for 22 Ga. needles. | Same (*1) |
| Specifications (Variations) | Needle length: 1 inch, 3/4 inch<br>Huber needle: 19G, 20G, 22G<br>Optional Y-site | Needle length: 1 inch, 3/4 inch<br>Huber needle: 19G, 20G, 22G<br>Optional Y-site | Same |

| | | | |
|---|---|---|---|
| Power injection resistance | Maximum flow rate<br>19G, 20G: < 5mL/s<br>22G: <2mL/s<br>Maximum pressure: 300psi | Maximum flow rate<br>19G, 20G: < 5mL/s<br>22G: <2mL/s | Same (*2) |
| **Features** | **Subject Device** | **Primary Predicate Device** | **Comparison** |
| Component & Material | Needle: Stainless Steel<br>Needle Cap: Polyethylene<br>ANSP Wing: Poly-propylene<br>Glue: Epoxy<br>Hub: Poly-vinyl choloride<br>Tubing: Poly-vinyl choloride (TOTM) | Unknown<br>(not identified in 510(k) summary) | Different (*3) |
| Anti-needle stick feature | Anti-needle stick protector is installed | Anti-needle stick protector is installed | Same (*4) |
| Sterilization | Ethylene Oxide Gas (ETO) | Ethylene Oxide Gas (ETO) | Same |
| Shelf Life | 3 years | 3 years | Same |

Discussion on the differences:

(*1) Intended Use and Indications for Use
The subject device and predicate device have the same intended use. Although there is some difference in wording, both the subject and predicate device are indicated for drug administration and blood sampling through implanted vascular port. Also, both of the devices are indicated for high-pressure injection. Based on the above, Indications for Use of the subject device is substantially equivalent to the predicate device.

(*2) Power Injection Resistance
The maximum flow rate for power injection is same in the subject device and in the predicate device. For the safety of use, the subject device also defines the maximum pressure as 300psi. We conducted the comparison test on their pressure resistance and the result demonstrated that the subject device is substantially equivalent to the predicate device.

(*3) Component and Material
Materials used for the predicate device are not identified in its 510(k) summary.
For the subject device, we conducted Biocompatibility testing in accordance with FDA guidance document *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process""*. The result demonstrated that there is no biocompatibility concern on the subject device.

(*4) Anti-needle stick feature
Both the subject device and the predicate device have an anti-needle stick protector. We conducted the comparison test on the operation of anti-needle stick protector. The result demonstrated that the subject device is substantially equivalent to the predicate device.
The anti-needle stick protector used in the subject device is the same one as used in the reference device K190233.

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

The following Performance Data were provided in support of the substantial equivalence (SE) determination of K-SHIELD Advantage PORT ACCESS INFUSION SET With High Pressure Tubing to the predicate device.

**Non-clinical bench testing**

| Test Performed | Applicable Standards | Results |
|---|---|---|
| **Luer Connector evaluation** | ISO 80369-7:2021 | **PASS** |
| **Physical test** | ISO 8536-8:2015, ISO 8536-14:2018<br>In-house (tensile strength test, clamp closure test, pressure resistance test) | **PASS** |
| **Coring test** | ASTM F3212-16(2023) | **PASS** |
| **Simulation test** | In-house (Flowability test using power injector, Operation test of Anti-needle stick protector) | **PASS** |
| **Needle test** | ISO 7864:2016 | **PASS** |
| **Chemical test** | ISO 8536-4:2019 | **PASS** |
| **Particulate contamination test** | USP <788> | **PASS** |
| **MR Safety** | FDA guidance document *"Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"* | **PASS** |

**Sterility, Transportation and packaging testing**

| Test Performed | Applicable Standards | Results |
|---|---|---|
| **EtO residual** | ISO 10993-7:2008/Amd.1:2019 | **PASS** |
| **Bacterial endotoxin** | USP <85> <161> | **PASS** |
| **Sterility test** | USP <71> | **PASS** |
| **Transportation & Package** | ISO 11607-1:2019/Amd.2023<br>ISO 11607-2:2019/Amd.2023<br>ASTM D4169-22 (-23e1) | **PASS** |

**Biocompatibility**

| Test Performed | Applicable Standards | Results |
|---|---|---|
| **Biocompatibility** | FDA guidance document *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process""*<br>ISO 10993-1:2018<br><br>Device categorization<br>- External Communicating Device: Blood Path, Indirect<br>- Contact duration: >24 hours to 30 days | **PASS** |

**Clinical testing**

Clinical testing was not performed to support this submission.

There were no unexpected results/ significant deviations associated with this testing.

***Discussion:*** 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 Advantage PORT ACCESS INFUSION SET with High Pressure Tubing performs as intended in the specified use conditions and comparably in terms of safety, effectiveness, and performance to the 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 Advantage PORT ACCESS INFUSION SET with High Pressure Tubing [subject device] when compared to the predicate device.

## IX. CONCLUSIONS

The K-SHIELD Advantage PORT ACCESS INFUSION SET with High Pressure Tubing [subject device] is substantially equivalent to the PowerLoc Safety Infusion Set (K060812)[predicate device] with respect to indications for use, treatment method and technological characteristics.