February 24, 2023

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

Re: K223810
Trade/Device Name: Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: January 27, 2022
Received: January 27, 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.
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)*
K223810

Device Name
Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH)

Indications for Use *(Describe)*
Female luer type
• The Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) is a sterile, non-invasive device used for connection with syringes when transferring blood specimen from a syringe to blood collection tube or blood culture bottle.

Male luer type
• The Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) is a sterile, non-invasive device used for connection with a female luer system and non-needle devices in order to collect blood specimen to blood collection tube.

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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K223810 - 510(K) Summary

Manufacturer:
SB-KAWASUMI LABORATORIES, INC.

Address:
3-25-4, Tonomachi, Kawasaki-ku
Kawasaki-shi, Kanagawa
210-8602, JAPAN

Corresponding Official/Contact:
Valerie Followell
Regulatory Consultant
Telephone Number: 847-400-6187
Email: v.followell@rcainc.com

Summary Date: **February 24, 2023**

Trade Name: Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH)

Common or Usual Name: Blood Collection Tubes, Vials, Systems, Serum Separators

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood specimen collection device

Product Code: JKA

Class: Class 2

Panel: Clinical Chemistry

Predicate Device: Kawasumi Multiple Sample Adapter with Pre-attached Holder has only one configuration with Male Luer Adapter (K190485)

Device Description:
The Kawasumi Multiple Sample Adapter with Pre-attached Holder (MBCH) is a sterile, single use device consisting of a plastic holder with a non-patient contacting stainless steel cannula covered with a rubber sheath and a luer adapter. There are two types of the device with difference in luer adapter type; male luer adapter type and female luer adapter type. The predicate device (K190485) is the male luer type and the proposed device is the female luer type, and the subject of this special 510(k) premarket notification submission.

- The male luer adapter type is used to collect blood specimen into blood collection tube by connecting to female luer connectors of vascular access devices such as peripheral, central catheter, Huber needle, etc. (predicate [Item number MBCH-01])

- The female luer adapter type is used to transfer blood from a syringe into blood collection tube or blood culture bottle. After drawing patient blood into a syringe, connect the female luer adapter of the device to the syringe. When inserting a tube, the blood is transferred into the tube using tube's vacuum. (subject [Item number MBCH-02])

The device is sterilized using Ethylene Oxide. The device is a prescription-use device intended to be used in hospitals or healthcare facilities.

Indications for Use:

Female luer type
• The Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) is a sterile, non-invasive device used for connection with syringes when transferring blood specimen from a syringe to blood collection tube or blood culture bottle.

Male luer type
• The Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) is a sterile, non-invasive device used for connection with a female luer system and non-needle devices in order to collect blood specimen to blood collection tube.

510(k) Summary Device Comparison Table

Feature of the Device	**Subject Device:** SB-KAWASUMI LABORATORIES, INC. Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH)	**Predicate Device:** Kawasumi Laboratories, Inc. Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH)	**Discussion/Comment:** The company name has been changed. Statement included in submission.
Item number (Model number)	MBCH-01 and MBCH-02	MBCH-01	Different The new item number MBCH-02 is added.
510(k) Number	K223810	K190485	-
Product Code	JKA	JKA	Same
Classification	21 CFR 862.1675	21 CFR 862.1675	Same
Classification Name	Tubes, Vials, Systems, Serum Separators, Blood Collection	Tubes, Vials, Systems, Serum Separators, Blood Collection	Same
Common Name	Blood Specimen Collection Device	Blood Specimen Collection Device	Same
Rx or OTC	Rx only	Rx Only	Same
Number of Uses	Single-Use	Single-Use	Same
Use Environment	Hospital and/or Healthcare Facility	Hospital and/or Healthcare Facility	Same
Indications for Use	Female luer type • The Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) is a sterile, non-invasive device used for connection with syringes when transferring blood specimen from a syringe to blood collection tube or blood culture bottle. Male luer type • The Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) is a sterile, non-invasive device used for connection with a female luer system and non-needle devices in order to collect blood specimen to blood collection tube.	The Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) is a sterile, non-invasive device used for connection with a female luer system and non-needle devices in order to collect blood specimen to blood collection tube.	Different Although there is a difference in where to connect the device, both types are used for collecting blood specimen to blood collection tube or blood culture bottle.

Intended Use	Same as the Indications for Use	Same as the Indications for Use	Same
Design Feature	Gauge: 20G Length (mm): 64.1± 0.3 Width (mm): 31 ± 0.3 x 23.5 ± 0.2	Gauge: 20G Length(mm): 64.1 ± 0.3 Width(mm): 31 ± 0.3 x 23.5 ± 0.2	Same
Luer Adapter Type	Female	Male	Different Differences do not change assertion of equivalence of devices
Number of Uses	Single-Use Rx Only	Single-Use Rx Only	Same
Materials **Hub**	Polycarbonate (PC)	Polycarbonate (PC)	Different Material is identical with the exception of its color. Supportive information included in submission.
Cannula	Stainless Steel	Stainless Steel	Same
Glue	Epoxy	Epoxy	Same
Silicone	Silicone Oil	Silicone Oil	Different Supportive information included in submission.
Sheath	Isoprene Rubber Not made with Natural Rubber Latex	Isoprene Rubber Not made with Natural Rubber Latex	Same
Holder	Polypropylene (PP)	Polypropylene (PP)	Same
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Shelf Life	3 years	3 years	Same

Technological Characteristics:
The Subject Device and the Predicate Device have similar technological characteristics. Both devices are sterile, single-use, non-invasive devices with a Pre-Attached Holder used for connection with a female luer system and non-needle devices in order to collect blood specimen to blood collection tube.

The Kawasumi Multiple Sample Adaptor with Pre-Attached Holder (Subject Device [MBCH-02]) is substantially equivalent to the Predicate Device [MBCH-01] with regard to technologic characteristics, materials, performance and intended use.

Non-Clinical Testing:
Non-Clinical Performance Testing was performed to ensure that the device meets design requirements and specifications and to confirm performance of the Kawasumi Multiple Sample Adaptor with Pre-Attached Holder [MBCH-02].

Test Item	Referenced standard	Result
Performance & Chemical Testing		
Luer connector evaluation	ISO 80369-7:2021	PASS
Simulation test	In-house	PASS
Physical test	ISO 1135-3:2016, in-house	PASS
Particulate contamination	USP<788>	PASS
Chemical test	ISO 1135-3:2016	PASS
Usability test	ISO 14971:2019 IEC 62366-1:2015 + Amd.1:2020	PASS
Sterilization, Transportation & Packaging		
EtO residual	ISO 10993-7:2008/Amd.1:2019	PASS
Bacterial endotoxin	USP <85>	PASS
Sterility test	USP <71>	PASS
Transportation & Package	ISO 11607-1:2019 ISO 11607-2:2019 ASTM D4169-16	PASS

Conclusion:
Based on the Non-Clinical Performance Testing conducted on the subject device, intended use, and principles of operation it may be concluded that the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (Subject Device [MBCH-02]) is substantially equivalent to the legally marketed Predicate Device [MBCH-01].