July 8, 2019

Kawasumi Laboratories, Inc.
% Lisa Michels
Regulatory Compliance Associates, Inc. (RCA)
10411 Corporate Drive, Suite 102
Pleasant Prairie, Wisconsin 53158

Re: K190485
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: June 6, 2019
Received: June 11, 2019

Dear Lisa Michels:

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,

for Nikhil Thakur
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)*
K190485

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

Indications for Use *(Describe)*
The Kawasumi Multiple Sample Adapter with Pr-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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510(K) Summary: K190485

Manufacturer:
Kawasumi Laboratories, Inc.

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2-15-2, Konan, Minato-Ku,
Tokyo, 108-6109, Japan

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Lisa L. Michels, J.D., M.S.O.L.Q
Regulatory Consultant

Telephone Number: (602)-935-2565
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Summary Date: July 3, 2019

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

Common or Usual Name: Blood Specimen Collection Device

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood specimen collection device

Product Code: JKA

Class: Class 2

Panel: Clinical Chemistry

Predicate Device: Becton Dickinson BD Vacutainer® Brand Multiple Sample Luer Adapter / BD Vacutainer® Safety-Lok Blood Collection Set with Pre-Attached Holder (K991088)

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 male luer adapter which is attached into the holder. This device is used to collect blood specimen by connecting to female luer connectors of vascular access devices such as peripheral, central catheter, Huber needle, etc. As this device can be connected to various devices with female luer adapter, it is called “multiple sample adapter”.

When blood is collected, the blood collection tube is placed over the cannula, pushing the rubber sheath back, allowing blood flow. After obtaining the correct amount of blood, the blood collection tube is removed from the holder. When the blood collection tube is removed, the rubber sheath extends back over the cannula and stopping blood flow. Blood collection may be continued by connecting additional blood collection tubes, if required.

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:
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.

Feature of the Device	**Subject Device:** Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH)	**Primary Predicate:** BD Vacutainer® Brand Multiple Sample Luer Adapter / BD Vacutainer® Safety-Lok Blood Collection Set with Pre-Attached Holder (K991088)	**Discussion/Comment:**
Product Code	JKA	JKA	Same
Classification	21 CFR 862.1675	21 CFR 862.1675	Same
Number of Uses	Single-Use Rx Only	Single-Use Rx Only	Same
Materials	Hub: Polycarbonate (PC)	Hub: Polystyrene	Biocompatibility Testing and Performance Testing was conducted to demonstrate SE.
	Cannula: Stainless Steel	Cannula: Stainless Steel	Same
	Glue: Epoxy	Glue: Epoxy	Same
	Silicon: Silicon Oil	Silicon: Silicon Oil	Same
	Sheath: Isoprene Rubber Not made with Natural Rubber Latex	Sheath: Isoprene Rubber Not made with Natural Rubber Latex	Same
	Holder: Polypropylene (PP)	Holder: Polypropylene (PP)	Same
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Indication for Use	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 Vacutainer Brand Multiple Sample Luer Adapter / BD Vacutainer® Safety-Lok Blood Collection Set with Pre-Attached Holder is a sterile, non-invasive device used to connect venous access device such as needles, blood collection sets, and infusion sets to blood collection tubes. They are also used in connection with non-needle devices for collection of blood from catheters. The Vacutainer Brand Luer Adapter is sold by itself and as a component of other Vacutainer Brand devices.	Similar-The difference is in the name of the device, this does not raise any questions of safety or effectiveness.
Design Feature	Gauge: 20G Length: 64.1 mm Width (A): 31.1 mm Width (B): 23.6 mm	Gauge: 20G Length: 64.3 mm Width (A): 30.5 mm Width (B): 24.9 mm	Non-Clinical Performance Testing was conducted to demonstrate SE.

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 (MBCH) (Subject Device) is substantially equivalent to the Becton Dickinson Vacutainer Brand Multiple Sample Luer Adapter / BD Vacutainer® Safety-Lok Blood Collection Set with Pre-Attached Holder (K991088) (Predicate Device) 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).

Test Name	Test Description
Comparative Testing	Comparative Evaluation Testing was conducted to verify that the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) has equivalent function and performance as the predicate device, the Becton Dickinson BD Vacutainer® Safety-Lok Blood Collection Set with Pre-Attached Holder (K991088). This Comparative Evaluation Testing assessed the following criterion of the subject and predicate devices: • Appearance and Measurement • Attachment and Detachment • Pressure Resistance • Connection Strength • Vacuum Tube Insertion and Removal • Chemical Resistance
Shelf Life Evaluation	• Physical Testing - Accelerated Aging Testing was conducted on the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) - [0 Month] / [6 Months] and [36 Months]. • Chemical Testing - Accelerated Aging Testing was conducted on the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) - [0 Month] and [36 Months].
Physical Testing Accelerated Aging **[0 Month]** **[6 Months]** **[36 Months]**	Physical Testing - Accelerated Aging Testing was conducted on the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) to ensure the functionality, performance, quality, and safety of the device to demonstrate substantial equivalence to the predicate device. Physical Testing on the Ethylene Oxide (EtO) Sterilized Kawasumi Multiple Sample Adapter with Pre-Attached Holder for [0 Months] / [6 Months] and [36 Months] aging by assessing the following: • Packaging Study / Stability Test - Transportation per ISTA 2A - Appearance per ISO 11607-1 2006/Amd.1:2014 - Seal Strength per ISO 11607-2: 2006/Amd.1:2014 - Dye Test per ISO 11607-2: 2006/Amd.1:2014 • Physical Study / Stability Test - Leakage per ISO 1135-3: 2016 5.2 - Tensile Strength per ISO 1135-3: 2016 5.3

	- Blood Taking Needle per ISO 1135-3: 2016 5.6
Chemical Testing Accelerated Aging **[0 Months]** **[36 Months]**	Chemical Testing - Accelerated Aging Testing was conducted on the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) to ensure the functionality, performance, quality, and safety of the device to demonstrate substantial equivalence to the predicate device. The following items were assessed on the [0 Months] and [36 Months] aging samples, per ISO 1135-3:2016. - Reducing matter - Metal ions - Titration acidity and alkalinity - Nonvolatile residue - Absorbance
Sterilization Product Adoption	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.
Sterility	Product Sterility Testing was performed according to United States Pharmacopeia <71> Stability Test.
EO Residuals	Residual Gas & Chemical Testing was conducted on the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) to ensure the functionality, performance, quality, and safety of the device per ISO 10993-7: Biological Evaluation of Medical Devices Part 7 – Ethylene Oxide Sterilization Residuals including: • Chemical Testing - Residual Gas & Chemical Testing - [0 Months] • Chemical Testing - [36 Months]
Particulate Contamination Testing	Particulate Contamination Testing was conducted on the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) to ensure the functionality, performance, quality, and safety of the device to demonstrate substantial equivalence to the predicate device. This Particulate Contamination Testing was conducted per ISO 1135-3:2016, Item 5.1 on MBCH with accelerated aging at 55°C, 138 days for real-time equivalent [36 Months]. The test procedure follows Annex A.1 of ISO 1135-3:2018.
Packaging	Packaging Integrity Testing was conducted to verify the integrity of the packaging. The tests included: • Transportation Test (ISTA 2A) • Appearance Test (ISO 11607-1:2006/Amd.1:2014) • Seal Strength Test (ISO11607-2:2006/Amd.1:2014) • Dye Test (ISO11607-2:2006/Amd.1:2014)
Luer Fitting Testing (Conformance to ISO 80369-7:2016) **[0 Months]** **[36 Months]**	Luer Fitting Testing [0 Months] and Luer Fitting Testing [36 Months] was conducted in accordance with ISO 80369-7:2016 - Small-Bore Connectors for Liquids and Gases in Healthcare Applications -- Part 7: Connectors for Intravascular or Hypodermic Applications to confirm that the products produced based on the output of the design conform to the needs of the user and the intended use. The dimensions of the MBCH were measured to verify the parts of the MBCH were within the tolerance range and conform the standard.
Biocompatibility	Biocompatibility Testing was conducted on the Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH) in accordance with ISO 10993-1:2009 (Fourth Edition 2009-10-15) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process including:

	• Cytotoxicity Testing per ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity • Sensitization Testing per ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization • Irritation or Intracutaneous Reactivity Testing per ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization • Acute Systemic Toxicity Testing per ISO 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity • Material-Mediated Pyrogenicity Testing per USP General Chapter <151> Pyrogen Test and ISO 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity • Hemocompatibility Testing per ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4:2017 Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood

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