September 28, 2018

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

Re: K172957
Trade/Device Name: Kawasumi Laboratories Blood Drawing Kit (BDK) System
Regulation Number: 21 CFR 864.9875
Regulation Name: Transfer set
Regulatory Class: Class II
Product Code: KSB, LHI, FMI
Dated: August 21, 2018
Received: August 28, 2018

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172957

Device Name
Kawasumi Laboratories Blood Drawing Kit (BDK) System

Indications for Use *(Describe)*
The Blood Drawing Kit with Antineedle Stick Protector is a single use, sterile transfer set designed for vascular access for blood withdrawal. Use of the Needleless Access Connector allows the clinician needle-free blood withdrawal when blood sampling is required. The Antineedle Stick Protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles. This device is not intended for blood transfusion.

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
(K172957)

I. SUBMITTER

Owner/Manufacturer:

Kawasumi Laboratories, Inc.
Shinagawa Intercity Tower B, 9th Floor 2-15-2, Konan, Minato-Ku,
Tokyo, 108-6109, Japan
Phone: (81)-3-5769-2663
Contact Person: Katsu Furuya

Date Prepared: September 12, 2017

II. DEVICE

Trade Name of Device: Kawasumi Laboratories Blood Drawing Kit (BDK) System

Common or Usual Name of Device: Blood Drawing Kit System

Classification Name: Set, Transfer (Blood Plasma)

Primary Classification Product Code and Classification Regulation:

- KSB (Set, Transfer – Blood/Plasma -21 CFR 864.9875)

Subsequent Classification Product Code(s) and Classification Regulation(s):

- LHI (Set I.V Fluid Transfer - 21 CFR 880.5440)
- FMI (Needle, Hypodermic, Single Lumen - 21 CFR 880.5570)

Device Class: Class II

III. PREDICATE DEVICE(S)

The Blood Drawing Kit (BDK) System is substantially equivalent to Kawasumi Laboratories' own predicate device(s) including the following Primary Predicate Device:

- **Kawasumi Laboratories Blood Drawing Kit - cleared under (K001043)**

IV. DEVICE DESCRIPTION

The Kawasumi Laboratories Blood Drawing Kit (BDK) System is a therapeutic device used to access a patient's vein for blood removal from the patient to a blood bag reservoir to aid in the treatment of a disease or other condition. The device is not intended for blood transfusion.

The Kawasumi Laboratories Blood Drawing Kit (BDK) System consists of a Blood Drawing Kit device that is designed with an integral Antineedle Stick Protector that provides a safety feature intended to minimize accidental needle stick injuries when the device is activated during removal from the patient's vein and may incorporate a needleless access connector site used for blood sampling.

The Blood Drawing Kit System is a single use, disposable Ethylene Oxide Sterilized medical device. Sterilization Validation was conducted per ISO 11135-1: 2007 – *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*. The Blood Drawing Kit System is considered blood path, indirect, limited contact (< 24 hours) per section 5.2.2 (a) of ISO 10993-1: 2009 - *Biological Evaluation of Medical Devices -Part 1: Evaluation and Testing within a Risk Management Process.*

The Kawasumi Laboratories Blood Drawing Kit (BDK) System is a sterile, single-use device that consists of the following components:
*(Y) means the fluid contact components

- Needle Protector
- Cannula (Y)
- Hub (Y)
- Wing (Y – skin contact only)
- Antineedle Stick Protector "K-Shield"
- Tubing (Y)
- Needleless Access Connector (NAC) Y-Site (Y)
- Clamp
- Blood Bag Unit Reservoir (Y)

The device is intended for use at healthcare facilities or in hospitals.

V. INDICATIONS FOR USE

The Blood Drawing Kit with Antineedle Stick Protector is a single use, sterile transfer set designed for vascular access for blood withdrawal. Use of the Needleless Access Connector allows the clinician needle-free blood withdrawal when blood sampling is required. The Antineedle Stick Protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles. The device is not intended for blood transfusion.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY PREDICATE DEVICE

The Comparison of Technological Characteristics of the Subject Device and the Primary Predicate Device (K001043) are shown in the table below:

Kawasumi Laboratories Blood Drawing Kit (BDK) System Table of Substantial Equivalence			
REGULATORY INFORMATION			
Device Name	***[Proposed Subject Device]*** **Kawasumi Laboratories Blood Drawing Kit (BDK) System**	***[Primary Predicate Device]*** **Kawasumi Laboratories Blood Drawing Kit (K001043)**	**Similarities/ Differences**

510(k) Status	Pending – K172957	K001043	
Device Classification Name	Set, Transfer (Blood, Plasma)	Set, Transfer (Blood, Plasma)	Same
Device Classification	Class II	Class II	Same
Product Code and Regulation Number	(KSB) 21 CFR 864.9875	(KSB) 21 CFR 864.9875	Same
Subsequent Product Code(s) and Regulation Number(s)	(LHI) 21 CFR 880.5440 (FMI) 21 CFR 880.5570	(LHI) 21 CFR 880.5440	Same
DESIGN FEATURES AND CAPABILITIES OF THE DEVICE			
Intended Use / Indication for Use	The Blood Drawing Kit with Antineedle Stick Protector is a single use, sterile set designed for vascular access for blood withdrawal. Use of the Needleless Access Connector allows the clinician needle-free blood withdrawal when blood sampling is required. The Antineedle Stick Protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles. This device is not intended for blood transfusion.	The Blood Drawing Kit is a sterile, single-use device used for therapeutic purposes to collect patient's blood into a blood bag reservoir. The collected blood is properly discarded and not intended for transfusion. This 510(k) Submission did not originally include the Antineedle Stick Protector. It was cleared for use with the BDK under K073257 and K102994.	BDK same as K001043; Antineedle Stick Protector same as K073257 and K102994
DESIGN FEATURES			
Dimensions, Gauge, Length, Width	Needle Gauge: 16 Length: 1450 mm including needle cap)	Needle Gauge: 16 Length: 1450 mm including needle cap)	Same
Venipuncture Needle	Option with the pre-attached venipuncture needle or option without the pre-attached venipuncture needle	Option with the pre-attached venipuncture needle or option without the pre-attached venipuncture needle	Same
Antineedle Stick Protector (ANSP) Option	Antineedle Stick Protector (ANSP) Option.	None	The Antineedle Stick Protector Option was cleared for use with the Blood Drawing Kit under K073257 and K102994.
Injection Option	Needleless Access Connector (NAC) Y-Site Option	None	NAC Y-Site Option is the Same as K073257 and K102994. The Needleless Access Connector (NAC) Y-Site Option was cleared for use with the Blood Drawing Kit under K073257 and K102994. This difference does not raise new questions of safety and effectiveness.
Sterilization Method	Ethylene Oxide Gas (ETO)	Autoclave (AC)	Different Method. SAL is identical. Differences do not raise new questions of safety and effectiveness
MATERIALS			
Needle Protector	Polyethylene (PE)	Polyethylene (PE) Polyvinyl Chloride (PVC) Poly-Propylene (PP)	Differences do not raise new questions of safety and effectiveness

Cannula	Stainless Steel	Stainless Steel	Same
Hub	Polycarbonate (PC)	Polyvinyl Chloride (PVC)	Differences do not raise new questions of safety and effectiveness
Wing	Polyvinyl Chloride (PVC)	None	Same as K073257 and K102994
K-Shield	Polypropylene (PP)	None	Same as K073257 and K102994
Tubing	Polyvinyl Chloride (PVC)	Polyvinyl Chloride (PVC)	Same
Injection Site (NAC-Y site)	Polycarbonate / Synthetic Polyisoprene	None	Same as K073257 and K102994
Clamp	Polypropylene (PP)	Polypropylene (PP)	Same
Bag Unit	Polyvinyl Chloride (PVC)	Polyvinyl Chloride (PVC)	Same

DISCUSSION OF TECHNOLOGICAL SIMILARITIES AND DIFFERENCES

Technological Characteristics and Substantial Equivalence

The Blood Drawing Kit (BDK) System is substantially equivalent in both function and use to the following Primary Predicate Device – Kawasumi Laboratories Blood Drawing Kit (cleared under K001043) as noted below:

- Kawasumi Laboratories Blood Drawing Kit (Primary Predicate Device cleared under K001043); and the
- Components including the K-Shield Antineedle Stick Protector (ANSP Option) and the Needleless Access Connector Site (NAC- Y Injector Site Option) used for blood sampling cleared under (K073257) and (K102994) for use with the Blood Drawing Kit (Primary Predicate Device cleared under K001043)]

These differences do not raise new questions of safety and effectiveness over the Primary Predicate Device. Therefore, the Blood Drawing Kit (BDK) System is substantially equivalent to the Primary Predicate Device based on the intended use of the device.

Summary of Nonclinical Performance Testing

The determination of substantial equivalence was based on an assessment of non-clinical performance data including the following nonclinical tests that have been submitted, referenced, and relied on in this premarket notification submission for a determination of substantial equivalence.

[Biocompatibility Testing]

The biocompatibility evaluation for the Blood Drawing Kit System was conducted in accordance with the following guidance documents and standards as recognized by the FDA:

- FDA Blue Book Memorandum #G95-1 *"Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,"* issued May 1, 1995;
- ISO 10993- 1 *"Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"*
- ISO 10993-2 *Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirements*
- ISO 10993-4 *"Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interaction with Blood [Including: Amendment 1 (2006)]*
- ISO 10993-5 *"Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity*
- ISO 10993-10 *"Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*
- ISO 10993-11 *"Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity*
- ISO 10993-12 *"Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials*

The following non-clinical performance testing data were provided in support of the substantial equivalence determination:

- Cytotoxicity Testing
- Skin Sensitization Testing
- Intracutaneous Reactivity Testing
- Acute Systemic Toxicity Testing

- Pyrogen Testing
- Hemolysis Testing

[Functional Performance Testing]

The functional performance testing for the Blood Drawing Kit System was conducted in accordance with the following guidance documents and standards as recognized by the FDA:

- FDA Guidance for Industry and FDA Staff: *Medical Devices with Sharps Injury Prevention Features*, issued on August 9, 2005
- ISO 3826-1:2003 – Plastic Collapsible Containers for Blood and Blood Components
- ISO 1135-3:1986 – Transfusion Equipment for Medical Use – Part 3: Blood-Taking Sets
- ISO 1135-4:2012 – Transfusion Equipment for Medical Use - Part 4: Transfusion Sets for Single Use
- ISO 594-2: Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings

The following non-clinical performance testing data were provided in support of the substantial equivalence determination:

- Physical Test for BDK (Non-Aging, 6 Months Aging and 3 Years Aging)
  - Visual Inspection of Set and Packing
  - Test for Leakage
  - Flow Regulator (Clamp Test)
  - Volume Marking Accuracy Test & Blockage Test
  - Function of Large K-Shield Antineedle Stick Protector (Activation Test)
  - Function Test of NAC Needleless Access Connector (NAC) Y-Site Option
  - Pull Strength Test
  - Sharpness Test
- Chemical Test for BDK (Non-Aging, 6 Months Aging and 3 Years Aging)
  - Test for Reducing (Oxidizable) Matter
  - Test for Metal Ions
  - Test for Titration Acidity or Alkalinity
  - Test for Non-Volatile Residue
  - Test for Absorbance

[Sterilization Testing / Sterility Testing / Packaging Testing]

The sterilization testing / sterility testing / packaging testing for the Blood Drawing Kit System was conducted in accordance with the following guidance documents and standards as recognized by the FDA:

- ISO 10993-7 *"Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals [Including Technical Corrigendum 1 (2009)]*
- 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
- ISO 11138-1: Sterilization of Health Care Products – Biological Indicators – Part 1: General Requirements
- ISO 11607-1: Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Sterile Barrier Systems and Packaging Systems [including Amendment 1 (2014)]
- ISO 11607-2: Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming Sealing and Assembly Processes [including Amendment 1 (2014)]
- ISO 11737-1: Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products [including Technical Corrigendum 1 (2007)]

	• ISO 14644-1: Cleanrooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness by Particle Concentration • ISO 14622-2: Cleanrooms and Associated Controlled Environments – Part 2: Monitoring to Provide Evidence of Cleanroom Performance related to Air Cleanliness by Particle Concentration The following non-clinical performance testing data were provided in support of the substantial equivalence determination: o Material Mediated Pyrogen Testing o Particulate Testing o Sterilization Validation Testing o Residual Gas Analysis Testing o Packaging Testing
Conclusions	The non-clinical performance data demonstrate that the Blood Drawing Kit (BDK) System is substantially equivalent to the Primary Predicate Device.