May 2, 2019

Kawasumi Laboratories, Inc.
% Valerie Followell
Regulatory Affairs Consultant
Regulatory Compliance Associates, Inc.
10411 Corporate Drive, Suite 102
Pleasant Prairie, Wisconsin 53158

Re: K190233
Trade/Device Name: K-Shield Advantage Port Access Infusion Set (PAIS)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, PTI
Dated: April 1, 2019
Received: April 4, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

for Tina Kiang, Ph.D
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)*

K190233

Device Name

K-Shield Advantage Port Access Infusion Set (PAIS)

Indications for Use *(Describe)*

The K-Shield Advantage Port Access Infusion Set (PAIS) is a safety port access device used to administer solutions to surgically implanted port.

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.

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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."

5. 510(k) SUMMARY

K190233

DATE: March 28, 2019

OWNER:

Kawasumi Laboratories, Inc.
Shinagawa Intercity Tower B
2-15-2, Konan,
Minato-ku, Tokyo, JAPAN 108-6109

CONTACT PERSON:

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DEVICE NAME:

Trade name:	K-Shield Advantage Port Access Infusion Set (PAIS)
Common name:	Set, IV Fluid Transfer
Classification:	set, administration, intravascular
Regulation Number:	21 CFR 880.5440
Class: **Product Code**:	Class II FPA
Secondary Product Code:	PTI

PREDICATE DEVICE(S): Previously cleared 510(k) for Kawasumi Laboratories, Inc., K-Shield Advantage Port Access Infusion Set

Predicate 510(k)	Device Name	Indication	Clearance date	Company
K123344	K-Shield Advantage Port Access Infusion Set (PAIS)	a safety port access device used to administer solutions to surgically implanted port.	03/07/2013	Kawasumi Laboratories, Inc.

DEVICE DESCRIPTION:

The K-Shield Advantage Port Access Infusion Set (PAIS) is a safety port access device used to administer solutions to a surgically implanted port. This device is designed utilizing a non-coring Huber needle to access the implanted port. The K-Shield Advantage PAIS has an integral safety device intended to protect against accidental needle stick injuries and infection caused by blood borne pathogens. Upon removal from the port, the anti-needlestick protector (ANSP) covers the needle tip protecting against accidental needle stick injuries.

The devices are disposable ethylene oxide sterilized medical devices which are constructed from non-coring needle (Huber needle), wing, tubing (either micro bore or standard bore), clamp, female conical fitting and locking cap. The device has optional injection site (needle injection, needleless access connector (NAC), or no injection site) and anti-needle stick protector (ANSP).

INDICATIONS FOR USE STATEMENT:

The K-Shield Advantage Port Access Infusion Set (PAIS) is a safety port access device used to administer solutions to surgically implanted port.

TECHNOLOGICAL CHARACTERISTICS:

The K-Shield Advantage Port Access Infusion Set (PAIS) is substantially equivalent to the predicate device with regard to technological characteristics, performance, and intended use.

The proposed K-Shield Advantage Port Access Infusion Set has minor enhancements to the original design of the predicate device. These modifications include strengthening the safety device feature, improving gripping point for easy cannulation and reducing bulkiness of the needle cap. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Table 5-1. Subject Device Comparison to Predicate Device for Substantial Equivalence

	Features	Subject Device	Predicate Device	
Regulatory	Device Name	K-Shield Advantage Port Access Infusion Set (PAIS)	K-Shield Advantage Port Access Infusion Set (PAIS)	Same
	510(k)Number	K190233	K123344	Same
	Applicant	Kawasumi Laboratories, Inc.	Kawasumi Laboratories, Inc.	Same
	Class	2	2	Same
	Product code	FPA, PTI	FPA	Same
	C.F.R. Section	880.5440	880.5440	Same
	Intended use	This product is a safety port access device used to administer solutions to surgically implanted port.	This product is a safety port access device used to administer solutions to surgically implanted port.	Same
Specification	Packaging	Blister rigid tray with heat sealed lid	Blister rigid tray with heat sealed lid	Same
	Size	Needle Gauge: 19G, 20G, 22G Needle Length: 1 inch, 3/4 inch Tube Length: 200mm (w/o NAC), 180mm x 100mm(NAC)	Needle Gauge: 19G, 20G, 22G Needle Length: 1 inch, 3/4 inch Tube Length: 200mm (w/o NAC), 180mm x 100mm(NAC)	Same
	Priming volume (mL)	Standard bore : 1.3 Micro bore(w/o NAC): 0.4 Micro bore(with NAC): 0.9	Standard bore : 1.3 Micro bore(w/o NAC): 0.4 Micro bore(with NAC): 0.9	Same
	Needle	Huber Needle	Huber Needle	Same
	Connection Luer	Female	Female	Same
	Tubing	Standard bore/ Micro bore	Standard bore/ Micro bore	Same
	Antineedle Stick Protector (ANSP)	**ANSP** ***Minor modification to ANSP**	ANSP	Different (but equivalent)
	Injection site	needleless access connector (NAC) / none	needleless access connector (NAC) / none	Same
	Component & Material	See Table 2	See Table 2	Different (but equivalent)
	Sterilization	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)	Same
	Shelf Life	3 years	3 years	Same

Table 5-2. Component and Material

Component	Fluid Path	Material (Subject device)	Material (Predicate device K123344)
Needle	Y	Stainless Steel	Stainless Steel
Needle Cap	N	**Polyethylene (PE)**	Poly-propylene (PP)
ANSP Wing	Y (*Skin contact)	Poly-propylene (PP)	Poly-propylene (PP)
Glue	N	Epoxy	Epoxy
Hub	Y	Poly-vinyl chloride (PVC)	Poly-vinyl chloride (PVC)
Tubing	Y	TOTM Poly-vinyl chloride (PVC)	TOTM Poly-vinyl chloride (PVC)

ASSESSMENT OF NONCLINICAL DATA:

Bench testing was performed and confirms that the device meets design requirements and specifications. The devices comply with the International standard ISO 8536-4:2010- Infustion equipment for medical use -Part 4: Infusion sets for single use, gravity feed [Including: Amendment 1 (2013)] mainly, to be used primarily in a hospital / healthcare facility setting. The devices were evaluated to be safe and effective as a medical device based on design verification test results.

Kawasumi Laboratories, Inc. conducts risk analysis according to the requirements of ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices for the modifications to the device. The identified risks were adequately mitigated and verified by means of bench testing.

The device continues to meet the same material testing standards and sterilization process standards as the predicate devices. Device verification testing of performance has been verified through functional and simulate use testing.

Table 5-3. List of nonclinical tests

Test item	Standard	Result
Transportation	ISTA 2A	Pass
Packaging test - Seal strength - Dye penetration test	ISO 11607-1:2006(Amd 2014)	Pass
Visual inspection	In house standard	Pass
Functionality of Anti-needle stick protector	In house standard	Pass
Test for tensile strength (ISO 8536-4)	ISO 8536-4:2010 (Amd 2013)	Pass
Test for tensile strength (In house)	In house standard	Pass
Test for tensile Strength (ISO 7864) *Cannula and hub	ISO 7864:2016	Pass
Leak test	ISO 8536-9:2016	Pass
Chemical test	ISO 8536-4:2010 (Amd. 2013)	Pass

Given the needle cap is not patient contacting, the biocompatibility testing of the modified feature was determined not to be necessary.

PERFORMANCE TESTING CAP REMOVAL FORCE

Modified K-Shield Advantage PAIS products (Evaluation of cap functionality)	
Purpose:	The needle cap used for the subject device (modified K-Shield Advantage PAIS) is changed into straw CAP, from T-CAP of predicate device (K123344). In order to make sure that the function of the needle cap has not changed, measurement of cap removal force is performed with the new and old caps.
Method:	The removal force was measured when removing the cap by hand from the product fixed on a force gauge. Sample size: N= 30 for each cap.
Acceptance Criteria:	The removal resistance of straw cap is lower than T-cap. (In-house criteria)
Result:	Conforms
Discussion and Conclusion:	Cap removal force was lower with straw cap compared to T-CAP. Moreover, as per the transportation test already performed there was no cap detachment due to the transportation. As a conclusion, it was confirmed that there was no change in the function of the needle cap due to this modification.

Simulated Use Testing (Sharps Injury Prevention testing):	K-Shield Advantage Port Access Infusion Set includes sharps injury prevention feature (Anti-needle Stick Protector; ANSP). As ANSP of the device was modified, simulated use testing was conducted to evaluate the safety and effectiveness of its function. The test was conducted as per ISO 23908:2011 and FDA Guidance – Medical Device with Sharp Injury Prevention Features. For all of effective samples (n=599) evaluated, proper activation of ANSP were observed. This result exceeds the pre-defined acceptance criteria. The result confirmed that the anti- needle stick function of the modified K-Shield Advantage PAIS works as safely and effectively as the predicate device.
CONCLUSIONS:	The K-Shield Advantage Port Access Infusion Set (PAIS) is substantially equivalent to the predicate device. Testing against established standards and guidelines for its intended use and results of the risk analysis demonstrate that the proposed device is substantially equivalent to the predicate device.