K102994

NOV - 3 2010

SPECIAL 510(K): DEVICE MODIFICATION SUMMARY

October 8, 2010

1. SUBMITTER

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CONTACT: Mr. Jack Pavlo

2. NAME OF DEVICE: Kawasumi Laboratories Arterial Venous Fistula Set with Antineedle Stick Protector, Blood Drawing Kit with Antineedle Stick Protector, and Phlebotomy Set with Antineedle Stick Protector

COMMON NAME: Arterial Venous Fistula Set, Blood Drawing Kit, Phlebotomy Set

PROPRIETARY NAME: K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector, K-Shield Blood Drawing Kit with Antineedle Stick Protector, and K-Shield Phlebotomy Set with Antineedle Stick Protector

[Note: K-Shield is a Registered Trademark for the Kawasumi brand of needle protection devices.]

CLASSIFICATION: Class II, Codified at 21 CFR 880.5570.

PRODUCT CODE NUMBER: FMI

3. PREDICATE DEVICE: Kawasumi Laboratories Large Wing Sets with Antineedle Stick Protector (K073257), Medisystems Masterguard (K932074) and the Becton Dickinson Vacutainer Brand Safety-Lok Blood Collection Set (K980414).

4. DESCRIPTION OF THE DEVICE: The K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector, K-Shield Blood Drawing Kit with Antineedle Stick Protector, and K-Shield Phlebotomy Set with Antineedle Stick Protector are sterile, single use devices commonly used to access a patient's vascular system for dialysis and blood withdrawal. The K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector and K-Shield Phlebotomy Set with Antineedle Stick Protector devices are comprised of a needle and wing assembly with tubing and a female luer connector. The K-Shield Blood Drawing Kit is comprised of a needle and wing assembly, tubing and a blood collection bag. The devices incorporate an integral antineedle stick protector used to prevent accidental needlestick injuries.

5. SIGNIFICANT PERFORMANCE CHARACTERISTICS: There are no new performance characteristics of this device compared to the substantially equivalent devices marketed for sale in interstate commerce. All devices are used to access a patient's vascular system for dialysis or for blood collection and provide an integral antineedle stick protector feature.

6.. INDICATIONS FOR USE:

(1) The K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector is a single use, sterile set designed for vascular access for dialysis. The antineedle stick protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles.

(2) The K-Shield Blood Drawing Kit with Antineedle Stick Protector is a single use, sterile set designed for vascular access for blood withdrawal. The antineedle stick protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles

(3) The K-Shield Phlebotomy Set with Antineedle Stick Protector is a single use, sterile set designed for vascular access for blood withdrawal. The antineedle stick device is an integral, active safety device intended to minimize accidental needles stick injuries when used to shield needles

7. TECHNOLOGICAL CHARACTERISTICS: The design and technological characteristics of the K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector, K-Shield Blood Drawing Kit with Antineedle Stick Protector, and the K-Shield Phlebotomy Set with Antineedle Stick Protector are substantially equivalent to the identified predicate devices. The design technological characteristics of the K-Shield devices are identical to K073257 with the exception of the modification to the antineedle stick protector. This modification improves the performance of the antineedle stick protector and has no significant impact on safety or effectiveness of the devices performance for their intended use.

8. SUMMARY OF NON-CLINICAL TESTING DATA: The following testing was performed to determine the safety and effectiveness of the K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector, K-Shield Blood Drawing Kit with Antineedle Stick Protector, and the K-Shield Phlebotomy Set with Antineedle Stick Protector use and assess the product's substantial equivalence to the listed predicate devices:

Test	Result
Kawasumi Internal Test: Wing Activation	PASS
Kawasumi Internal Test: Wing Deactivation	PASS
Kawasumi Internal Test: Defeat Llocking Mechanism	PASS

9. SIMULATED CLINICAL OBSERVATIONS: Kawasumi Laboratories performed a simulated use study to determine the safety and effectiveness of the Antineedle Stick Protector for use with winged needle sets. The study objectives were to identify possible antineedle stick protector design problems, and /or directions for use and labeling deficiencies, and to gain information for designing a user training program to facilitate proper use of the antineedle stick protector in the clinical setting.

   Results: The simulated use study was successful. No needle sticks occurred during the trial. Comments on the Questionnaires did not indicate any problems in using the proposed Kawasumi winged needle sets with antineedle stick protectors.

10. PERFORMANCE DATA: Kawasumi Laboratories believe that the results of these tests show that the device is suitable for its intended use.

11. CONCLUSIONS: The K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector, K-Shield Blood Drawing Kit with Antineedle Stick Protector, and K-Shield Phlebotomy Set with Antineedle Stick Protector are substantially equivalent to the identified predicate devices and performs as well as the predicate devices Large Wing Sets with Antineedle Stick Protector (073257), Medisystems Masterguard (K932074) and the Becton Dickinson Vacutainer Safety-Lok Blood Collection Set (980414) for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kawasumi Laboratories America, Incorporated
C/O Jack Pavlo
4723 Oak Fair Boulevard
Tampa, Florida 33610

NOV - 3 2010

Re: K102994
Trade/Device Name: K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector, K-Shield Blood Drawing Kit with Antineedle Stick Protector, K-Shield Phlebotomy Set with Antineedle Stick Protector
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 8, 2010
Received: October 8, 2010

Dear Mr. Pavlo:

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

NOV - 3 2010

510(k) Number (if known): K102994

Device Name: K-Shield Arterial Venous Fistula Set with Antineedle Stick Protector,
K-Shield Blood Drawing Kit with Antineedle Stick Protector,
K-Shield Phlebotomy Set with Antineedle Stick Protector

Indications For Use:

Name: Kawasumi A.V. Fistula Set
Intended Use: This device is intended to be used to access a vein or artery and to be used as a conduit to connect to blood tubing lines for performing patient hemodialysis. The device 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 or artery.

Name: Kawasumi Laboratory Blood Drawing Kit
Intended Use: This 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. This device is not intended for blood transfusions. The device 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.

Name: Kawasumi Laboratories Phlebotomy Set
Intended Use: This device is intended to be used to access a patient's vein and as a conduit for blood removal to a vacuum bottle to aid in the treatment of a disease or other condition. The device 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for RLC Nov 1, 2010
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102994