FEB 2 6 2003

K023917

EXHIBIT 29

510(k) SUMMARY

1. **Submitter**

Kawasumi Laboratories, Inc.
3-28-15 Minami-Ohi
Shinagawa-Ku, Tokyo 140 Japan
Phone: 81-3-376-1151
Fax: 81-3-376-3235
Contact: Mr. K. So

Authorized Contact

Kawasumi Laboratories America, Inc.
5905 C Hampton Oaks Parkway
Tampa, Fl 33610
Phone: 813-630-5554
Fax: 813-630-5033
Contact: Mr. Jack Pavlo

2. **Name of Device**: Winged Needle Sets with an Antineedle Stick Protector

   Common Name: Needle stick protector

3. **Predicate Device**: Becton Dickinson Vacutainer Brand Safety-Lok Blood Collection Set
   Kawasumi Winged Collection Set w/ Multi-Sample Luer Adapter
   Kawasumi Small Vein Infusion Set

4. **Description of the Device**: The Antineedle Stick Protector is a polymeric device designed to be used integral with winged needle sets and shields the needle when the needle with hub and wing assembly is removed from the patient

5. **Intended Use**: The Antineedle Stick Protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles for Kawasumi products manufactured with a wing and needle assembly for solution infusion and blood sampling.

6. **Technological Characteristics**: The Antineedle Stick Protector is substantially equivalent to the Becton Dickinson Vacutainer Brand Safety-Lok Blood Collection Set, Kawasumi Winged Collection Set w/ Multi-Sample Luer Adapter, and Kawasumi Small Vein Infusion Sets. The antineedle stick protector is activated in a different manner than the BD Safety-Lok Blood Collection Set, but achieve the same results. In both devices, the needle tip is protected inside the device after use.

7. **Performance Data**: Kawasumi Laboratories has conducted a successful simulated use study to determine the acceptability of this device for use to minimize accidental needlestick injuries. Kawasumi Laboratories believes the successful simulated use study shows the device is suitable for its intended use and is substantially equivalent to the predicate device.

8. **Conclusions**: The device is as safe as the predicate device and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Kawasumi Laboratories, Incorporated
C/O Mr. Donald Stone
Kirkpatrick & Lockhart LLP
1800 Massachusetts Avenue, N.W. Suite 200
Washington, DC 20036

Re: K023917
Trade/Device Name: Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector, Small Vein Infusion Set with Antineedle Stick Protector
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 12, 2003
Received: February 13, 2003

Dear Mr. Stone:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 12

Indications for Use

510(k) Number: K023917

Device Name: Small Vein Infusion Set with Antineedle Stick Protector

Indications for Use: The Small Vein Infusion Set with Antineedle Stick Protector is a single use, sterile device used for peripheral venous access for solution administration or blood collection. The Antineedle Stick Protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles.

Device Name: Winged Collection Set with Multi-Sample Luer Adapter and Antineedle Stick Protector

Indications for Use The Winged Collection Set with Multi-Sample Luer Adapter and Antineedle Stick Protector is a single use, sterile, blood collection device used for peripheral venous access for blood sampling. The Antineedle Stick Protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield needles.

Patricia Cucenta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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