K061197

EXHIBIT 16

JUN 30 2006

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. Kuroiwa

U.S. AGENT:

KAWASUMI LABORATORIES AMERICA, INC
4723 Oak Fair Blvd.
Tampa, FL 33610
PHONE: (813) 630-5554
FAX: (813) 630-5033
CONTACT: Mr. Jack Pavlo

2. NAME OF DEVICE: Kawasumi Laboratories Empty Solution Container
COMMON NAME: Empty Solution Container
PROPRIETARY NAME: Empty Solution Container
CLASSIFICATION: Class II, Codified at 21 CFR 807.92.
CLASSIFICATION PANEL: General Hospital
PRODUCT CODE NUMBER: KPE

3. PREDICATE DEVICE: Abbott Laboratories Empty Container

4. DESCRIPTION OF THE DEVICE: The device comprises of a plastic bag with an entry port used for the introduction of solution(s) into the bag and two ports for accessing the bag with a solution administration set

5. SIGNIFICANT PERFORMANCE CHARACTERISTICS: There are no new performance characteristics of this device compared to the substantially equivalent device marketed for sale in interstate commerce. Both containers are used to hold solution commonly used in hospitals for the delivery of the solution to the patient.

6. INTENDED USE: The Empty Solution Container is a sterile, single use device used as a reservoir for the purpose of administering solution to a patient. The Empty Solution Container is filled with the desired solutions(s) commonly used in hospitals for the administration of the solution(s) to the patient. The bag is discarded after use.

6. TECHNOLOGICAL CHARACTERISTICS: There are no technological characteristics of this device to the substantially equivalent device from Kawasumi Laboratories being marketed for sale in interstate commerce.

7. PERFORMANCE DATA: Kawasumi Laboratories has conducted biocompatibility tests on the body fluid contacting material portions of the device and KL believes the biocompatibility data show the device is suitable for its intended us.

8. CONCLUSIONS: The device meets all the biocompatibility and pyrogenicity test requirements. Therefore, it is 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

JUN 30 2006

Mr. Jack Pavlo
Technical Services Manager
Kawasumi Laboratories America, Incorporated
4723 Oak Fair Boulevard
Tampa, Florida 33610

Re: K061197
Trade/Device Name: Empty Solution Container
Regulation Number: 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: April 25, 2006
Received: April 28, 2006

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.

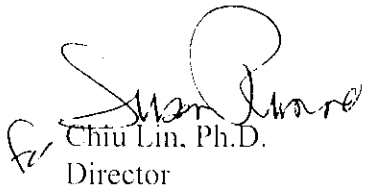
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT 13

Indications for Use

510(k) Number (if known): K061197

Device Name: Empty Solution Container

Indications For Use:

The Kawasumi Laboratories Empty Solution Container is a sterile, single use device used as a reservoir for the purpose of administering solution to a patient. The Empty Solution Container is filled with the desired solution(s) commonly used in hospitals. After use, the bag is discarded.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

[signature]

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

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