MAR - 8 2000

K994323

510(K) SUMMARY

1. SUBMITTER

KAWASUMI LABORATORIES, INC.
3-28-15 MINAMI-OHI
OAKS PARKWAY
SHINAGAWA-KU, TOKYO 140 JAPAN
PHONE:81-3-376-1151
FAX: 81-3-376-3235
CONTACT: MR. S. SUWA

AGENT

KAWASUMI LABORATORIES AMERICA, INC.
ARE NO NEW 5909 C HAMPTON

TAMPA, FL 33610
PHONE: 813-630-5554
FAX: 813-630-5033
CONTACT: MR. JACK PAVLO

2. **NAME OF DEVICE**: KAWASUMI LABORATORIES PHLEBOTOMY SET

COMMON NAME: PHLEBOTOMY SET

3. **PREDICATE DEVICE**: ABBOTT LABORATORIES BLOOD COLLECION SET

4. **DESCRIPTION OF THE DEVICE**: A STERILE, SINGLE USE DEVICE FOR WITHDRAWING BLOOD..

BASIC CONCEPT: A CONDUIT USED FOR WITHDRAWING BLOOD FROM THE PATIENT'S VEIN TO A VACUUM BOTTLE RESERVOIR

SIGNIFICANT PERFORMANCE CHARACTERISTICS: THERE ARE NO SIGNIFICANT PERFORMANCE CHARACTERITICS OF THIS DEVICE COMPARED TO SUBSTANTIALLY EQUIVALENT DEVICES MARKETED FOR SALE IN INTERSTATE COMMERCE. THE DEVICE IS USED TO REMOVE BLOOD FROM A PATIENT INTO A VACUUM BOTTLE.

5. **INTENDED USE**: THE PHLEBOTOMY SET IS USED TO REMOVE BLOOD FROM A PATIENT INTO A VACUUM BOTTLE.

6. **TECHNOLOGICAL CHARACTERISTICS**: THERE ARE NO TECHNOLOGICAL CHARACTERISTICS OF THIS DEVICE TO THE SUBSTANTIALLY EQUIVALENT DEVICE FROM ABBOTT 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 USE.

8. **CONCLUSIONS**: THE DEVICE MEETS ALL BIOCOMPATIBILITY AND PYROGENICITY TEST REQUIREMENTS. THEREFORE, IT 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

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Kawasumi Laboratories, Company, Limited
C/O Donald R. Stone, Esq.
McKenna and Cuneo, L.L.P.
1900 K Street N.W.
Washington, DC 20006

Re: K994323
Trade Name: Kawasumi Laboratories Phlebotomy Set
Regulatory Class: II
Product Code: LHI and KSB
Dated: December 21, 1999
Received: December 22, 1999

Dear Mr. Stone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

DEVICE NAME: KAWASUMI LABORATORIES PHLEBOTOMY SET

INDICATIONS FOR USE: A CONDUIT FOR BLOOD REMOVAL FROM A PATIENT TO A VACUUM BOTTLE TO AID IN THE TREATMENT OF A DISEASE OR OTHER CONDITION.

Patricia Cucanda

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994323