K974829

FEB 12 1998

510(K) SUMMARY

1. SUBMITTER

KAWASUMI LABORATORIES, INC.
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SHINAGAWA-KU, TOKYO 140 JAPAN
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CONTACT: MR. SHUJI SUWA

U.S. AGENT:

KAWASUMI LABORATORIES AMERICA, INC
5905 C HAMPTON OAKS PARKWAY
TAMPA, FL 33610
PHONE:
FAX
CONTACT: MR. JACK PAVLO

2. NAME OF DEVICE: KAWASUMI LABORATORIES NON-PVC FLUID PATH PORT ACCESS INFUSION SET (WITH AND WITHOUT INJECTION SITE)

COMMON NAME: WINGED ACCESS SET

CLASSIFICATION: UNCLASSIFIED

3. PREDICATE DEVICES: KAWASUMI LABORATORIES PORT ACCESS INFUSION SET AND THE PRN NONCOR PORT INFUSION SET

4. DESCRIPTION OF THE DEVICE: A NON-PVC PORT ACCESS INFUSION SET IS A STERILE, SINGLE USE DEVICE WITH A NEEDLE, WING, NON-PVC I.D. TUBING AND NON-PVC COMPONENTS USED FOR ACCESSING IMPLANTED MEDICATION PORTS.

BASIC CONCEPT: A DEVICE USED FOR ACCESSING AN IMPLANTED MEDICATION PORT BY PUNCTURING THE SEPTUM OF THE MEDICATION PORT USED FOR THE DELIVERY OF MEDICATION. FLUID ADMINISTRATION THROUGH THE NON-PVC FLUID PATH PORT ACCESS INFUSION SET ARE THOSE GENERALLY USED IN HOSPITALS AND FOR CHEMOTHERAPY.

SIGNIFICANT PERFORMANCE CHARACTERISTICS: THERE ARE NO NEW PERFORMANCE CHARACTERISTICS OF THIS DEVICE WHEN COMPARED TO SUBSTANTIALLY EQUIVALENT DEVICES MARKETED FOR SALE IN INTERSTATE COMMERCE. BOTH DELIVER FLUIDS TO THE VASCULAR SYSTEM THROUGH A NON-REACTIVE MATERIAL.

5. INTENDED USE: THE NON-PVC PORT ACCESS INFUSION SET IS ROUTINELY USED TO ACCESS IMPLANTED MEDICATION PORTS FOR THE DELIVERY OF MEDICATIONS.

6. TECHNOLOGICAL CHARACTERISTICS: NO NEW TECHNOLOGICAL CHARACTERISTICS OF THIS DEVICE EXIST WHEN COMPARED TO SUBSTANTIALLY EQUIVALENT DEVICES INCLUDING KAWASUMI AND PRN SETS BEING MARKETED FOR SALE IN INTERSTATE COMMERCE. THIS DEVICE USES A COEXTRUDED TUBE WHICH DOES NOT EXPOSE THE FLUID DELIVERED INTRAVASCULARLY TO PVC.

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.

THE DEVICE MEETS THE LIMULUS AMEBOCYTE LYSATE ("LAL") TEST DESCRIBED AT "(85) BACTERIAL ENDOTOXINS TEST", USP XXII, PP 1493-1495.

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

Kawasumi Laboratories, Incorporated
C/O Donald R. Stone
McKenna and Cuneo, L.L.P.
1575 Eye Street, N.W.
Washington, DC 20005

FEB 12 1998

Re: K974829
Trade Name: Non-PVC Fluid Path Port Access Infusion Set with and without Injection Site
Regulatory Class: Unclassified
Product Code: LJT
Dated: November 10, 1997
Received: December 24, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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

K974829

EXHIBIT B1.

INDICATIONS FOR USE

DEVICE NAME: NON-PVC FLUID PATH PORT ACCESS INFUSION WITH AND WITHOUT INJECTION SITE

INDICATIONS FOR USE:

INFUSION OF FLUIDS, INCLUDING THOSE CONTAINING MEDICATIONS, FROM A CONTAINER TO A PORT IMPLANTED IN, OR OTHERWISE ATTACHED TO, A PATIENT TO AID IN THE DIAGNOSIS OR TREATMENT OF DISEASE OR OTHER CONDITIONS.

Patricia Cusenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974829

Prescription Use ✓
(Per 21 CFR 801.109)