DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1997

Welcon, Inc.
% Ms. Pamela Papineau
Delphi Medical Device Consulting
50 Brewster Street
Pawtucket, Rhode Island 02860

Re: K971764
Welcon Hue-Vu™ Urinary Drainage Bag
Dated: May 9, 1997
Received: May 13, 1997
Regulatory class: II
21 CFR §876.5250/Product code: 78 KNX

Dear Ms. Papineau:

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Welcon, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Welcon chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	**Welcon Hue-Vu™ Urinary Drainage Bag**
Owner/Operator:	Welcon, Inc. 99 Hartford Avenue Providence, RI 02909
Distributed by:	Welcon, Inc. 303 Main Street, Suite 300 Fort Worth, TX 76102
Manufacturing Site:	Pacific Device, Inc. 8572 Spectrum Lane San Diego, CA 92121
Device Generic Name:	Urinary drainage bag
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (21CFR 876.5250).
Predicate Devices:	Urinary Drainage Unit (Catalog #6220) Intermed, Inc. Sparta, New Jersey 07871 K780837 Bard Center Entry Closed System Urinary Drainage Bag (Catalog #153509) Bard Urological Division Covington, GA 30209 K844810/K940206

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Product Description:
The Welcon Hue-Vu™ Urinary Drainage Bag is a 2000 ml capacity vented vinyl urine collection receptacle intended to be used with an indwelling catheter. The bag has a hanging hook at the top, and is equipped with a sampling port near the catheter connector. The inlet tubing has an anti-reflux valve to prevent backflow. A vent allows air to escape the bag as urine enters. A Hue-Vu™ color strip label is affixed to the front of the bag, and is used to compare and record the color of the urine collected in the bag.

Indications for Use:
The drainage bag is indicated for collection of urine when used with an indwelling catheter.

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Safety and Performance:
Substantial equivalence for this device was based solely on design and performance characteristics; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the Welcon Hue-Vu™ device are identical to those of the predicate devices.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the Welcon Hue-Vu™ Urinary Drainage Bag has been shown to be safe and effective for its intended use.

510(k) Number (if known): _____

Device Name: Welcon Hue-Vu™ Urinary Drainage Bag

Indications for Use:

The Welcon Hue-Vu™ Urinary drainage Bag is indicated for use for the collection of urine when used with an indwelling catheter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971764

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)