FEB 2 7 1998

Performance Plus, Inc.
Summary of Safety and Efficacy

K974082

Applicant Information:

Performance Plus, Inc.
801 South Church St., Suite 7
Mount Laurel, NJ 08054

510(k) Summary Prepared by:

Carolann Kotula
Official Correspondent for Performance Plus, Inc.
c/o mdi Consultants, Inc.
55 Northern Boulevard
Great Neck, NY 11021

Phone: (516) 482-9001
Fax: (516) 482-0186

Date 510(k) Summary Prepared: October 22, 19997

Name/Classification of the Device:

Classification Name:	External penile rigidity device (product code 78LKY)
Common Name:	Penile constriction ring Penile vacuum pump
Proprietary Name:	The Performance Plus Confidence Rings The Performance Plus Erection Inducer Device (E.I.D.)
Classification/Panel:	External penile rigidity devices have not been classified. The Urology panel would classify this device.

Comparative Information: These devices are identical to the predicates, K891125(Confidence Rings) and K896060 (E.I.D) in materials,dimensions, performance, and intended use. The labeling is changed to provide the information needed for safe over the counter use of these devices.

Description of the Subject Devices: The Performance Plus Confidence rings are soft, pliable rings with a tab for removal. The E.I.D. system consists of a vacuum tumescence pump, a vacuum chamber with inserts, Confidence rings, lubricating gel, instructions for use, and a carrying case.

Intended Use: Performance Plus Confidence Rings are devices that are placed around the base of the penis to help sustain an erection. An erection is achieved when the spongy corpora of the penis fills with arterial blood during sexual stimulation. In certain men, the penis may not become fully erect because the penile venous system drains too rapidly or leaks blood from the corpora. The rings operate by limiting venous return from the major superficial veins of the penis.

The E.I.D. system is an external erection device that induces penile rigidity though vacuum assisted vascular engorgement of the penis. Once erection is achieved, a Confidence ring is placed at the base of the penis to sustain the erection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 1998

Performance Plus, Inc.
c/o Ms. Carolann Kotula
Vice President RA/QA
MDI Consultants, Inc.
55 Northern Blvd.
Great Neck, NY 11021

Re: K974082
Performance Plus Confidence Rings - OTC
Performance Plus Erection Inducer Device (E.I.D.) - OTC
Dated: January 31, 1998
Received: February 3, 1998
Unclassified/Procode: 78 LKY

Dear Ms. Kotula:

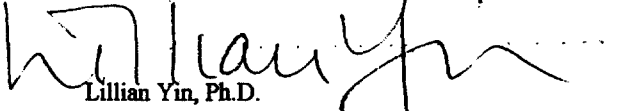
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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/dsma/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

Performance Plus Inc.
510(k) Notification: OTC Labeling
Confidence Rings/Erection Inducer Device

Attachment 3

510(k) Number (if known): K974082

Device Name: Performance Plus, Inc, Confidence Rings and Erection Inducer Device.

Indications for Use:

Performance Plus Confidence Rings are devices that are placed around the base of the penis to help sustain an erection. An erection is achieved when the spongy corpora of the penis fills with arterial blood during sexual stimulation. In certain men, the penis may not become fully erect because the penile venous system drains too rapidly or leaks blood from the corpora. The rings operate by limiting venous return from the major superficial veins of the penis.

The E.I.D. system is an external erection device that induces penile rigidity though vacuum assisted vascular engorgement of the penis. Once erection is achieved, a Confidence ring is placed at the base of the penis to sustain the erection.

(Please Do Not Write Below this Line/Continue on Another Page if Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974082

Prescription Use _____ OR Over the Counter Use ✓
(per 21 CFR 801.109)