

K980291
P171

510(k) Summary
Imagyn Medical Technologies, Inc.
Impower™ Vacuum Erection Device

I. General Information on Submitter:

Name: Imagyn Medical Technologies, Inc.
Address: 5 Civic Plaza, Suite 100
Newport Beach, CA 92660
Phone: (714) 668-5858
Fax: (714) 668-5856

MAR 11 1998

Name of Contact Person: Ronald H. Bergeson
Date Summary Prepared: January 23, 1998

II. General Information on Device

Name: Impower System Vacuum Erection System - OTC

III. Classification Name: External Penile Rigidity Device

IV. Predicate Devices: Impower (Catalyst) System (510(k) No. K920409)

I. Description of the Device:

The Imagyn Medical Technologies, Inc.'s Impower System vacuum erection device ("Impower") consists of a vacuum pump, tension rings, seal rings, clear plastic cylinder, and a tube of personal lubricant.

V. Intended Use:

The Impower device is used to assist in creating and maintaining an erection suitable for sexual intercourse. This device is intended for the treatment or management of erectile dysfunction/impotence.

VI. Substantial Equivalence

The Impower uses the same vacuum method and technological characteristics to create and maintain an erection as the predicate device. It also uses the same components and materials as the predicate device. Therefore, the Impower device is substantially equivalent to its predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ronald H. Bergeson
Corporate Director of Regulatory Affairs
Imagyn Medical Technologies
27651 La Paz Road
Laguna Niguel, CA 92677

Re: K980291

Imagyn Medical Technologies Impower™
Vacuum Erection Device - OTC

Dated: January 23, 1998

Received: January 26, 1998

MAR 11 1998

Unclassified/Procode: 78 LKY

Dear Mr. Bergeson:

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

ODE INDICATIONS FOR USE FORM

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510 (k) Number (if known): K980291

Device Name: Impower Vacuum Erection Device-OTC

Indications for Use:

This device is intended for the treatment or management of erectile dysfunction/impotence.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Rathbone
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980291

Prescription Use _____
(Per 21 CFR 801.1091)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)