

K974173
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11.

510(k) Summary

**Imagyn Medical Technologies, Inc.
ErecAid™ Vacuum Erection and StayErec® Tension Ring Devices**

I. General Information on Submitter:

Name: Imagyn Medical Technologies, Inc.
Address: 5 Civic Plaza, Suite 100
Newport Beach, CA 92660
Phone: (714) 720-8855
Fax: (714) 720-8809

Name of Contact Person: Ronald H. Bergeson
Date Summary Prepared: November 4, 1997

II. General Information on Device

Name: ErecAid® System Vacuum Erection System - OTC
StayErec® Tension Rings - OTC

Classification Name: External Penile Rigidity Device

III. Predicate Devices: ErecAid System Classic (510(k) No. K841257)
ErecAid System Esteem Battery (510(k) No. K912736/A)
StayErec Tension Rings (510(k) No. K901318)

IV. Description of the Device:

The Imagyn Medical Technologies, Inc. ErecAid System Classic vacuum erection system ("ErecAid") consists of a vacuum pump, tension rings, insert ring, clear plastic cylinder, and a tube of personal lubricant. The StayErec Tension Ring consists of a ring of the same material, and used in the same manner as the predicate device.

V. Intended Use:

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

VI. Substantial Equivalence

The ErecAid uses the same vacuum method and technological characteristics to create and maintain an erection as the predicate devices. It also uses the same components and materials as the predicate devices. Therefore, the ErecAid and StayErec devices are substantially equivalent to its predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1998

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

Re: K974173
ErecAid® Systems Classic, Esteem Manual, and Esteem
Battery Models-OTC and StayErec® Tension Rings-OTC
Dated: January 23, 1998
Received: January 26, 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 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

510 (k) Number (if known): K974173

Device Name: ErecAid® System Vacuum Erection Device-OTC, and StayErec® System Tension Rings-OTC

Indications for Use:

ErecAid® System-OTC and StayErec® System Tension Rings-OTC

These devices are 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 K974173

Prescription Use _____
(Per 21 CFR 801.1091)

OR

Over-The-Counter Use
(Optional Format 1-2-96)