

JUN 25 1998

Premarket Notification [510(k)] Summary

Submitter's Name: Repro-Med Systems, Inc.

Address: 24 Carpenter Road
 Chester, NY 10918

Telephone: 800-624-9600

Fax: 914-469-5518

Contact Person: Andrew Sealton

Date 510(k) Summary Prepared: June 24, 1998

510(k) Number: **K981506**

Trade or Proprietary Name(s): RESTORE Vacuum Erection Device
Common Name: External Penile Rigidity Device
Classification Name: Vacuum Pump And Constriction Rings

Predicate Device(s): Erecaid System Classic (K841257)
Erecaid System / Stay Erec System (K974173)
Pro-Long Rings (K904485)

Device Description:

The RESTORE Vacuum Erection Device consists of a vacuum pump, ABS plastic vacuum cylinder, connecting PVC tubing, cylinder end cap, cushion seal, constriction rings, a tube of personal water-based lubricant and a convenient travel case.

Intended Use:

Intended Use and Indications

The RESTORE Vacuum Erection Device consists of two main parts: the vacuum pump and constriction rings.

Vacuum Pump – used to create an erection in men with erectile dysfunction by means of an applied vacuum to the penis, which draws blood into the penile corpora cavernosa causing the penis to become erect and rigid.

Constriction Ring – used to maintain penile rigidity in men with erectile dysfunction by restricting penile venous outflow after the patient has obtained an erection with the aid of a vacuum pump.

Summary of Technological Characteristics to Predicate Device:

The RESTORE Vacuum Erection Device vacuum pump is substantially equivalent to the first two (2) predicate devices listed above. Repro-Med Systems, Inc. owns the proprietary technology for the Osbon products (predicate devices) and has been the sole manufacturer for the Erecaid System Classic vacuum pump since 1989.

The RESTORE Vacuum Erection Device Constriction Rings are identical to the Pro-Long rings (predicate device). Repro-Med has entered into a contractual agreement to market the Pro-Long rings as a component of the RESTORE device.

All component materials are identical to the named predicate devices and, therefore, the RESTORE Vacuum Erection Device is substantially equivalent.

JUN 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Andrew I. Sealton
President
Repro-Med Systems, Inc.
24 Carpenter Road
Chester, New York 10918Re: K981506
RESTORE™ Vacuum Erection Device - OTC
Dated: April 24, 1998
Received: April 27, 1998
Regulatory Class: Unclassified
Product Code: 78 LKY

Dear Mr. Andrew I. Sealton:

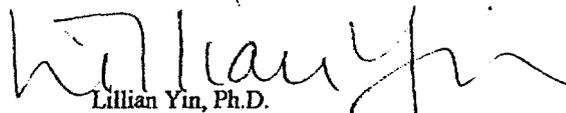
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known):

K981506

Device Name:

RESTORE Vacuum Erection Device

Indications For Use:

The RESTORE Vacuum Erection Device consists of two main parts: the vacuum pump and constriction ring. Intended use statements for these are as follows.

Vacuum Pump (intended use) - used to create an erection in men with erectile dysfunction by means of an applied vacuum to the penis, which draws blood into the penile corpora cavernosa causing the penis to become erect and rigid.

Constriction Ring (intended use) - used to maintain penile rigidity in men with erectile dysfunction by restricting penile venous outflow after the patient has obtained an erection with the aid of a vacuum pump.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rakesh P. Rathinam /
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981506

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use