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K993343
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510(K) SUMMARY
for
ERECXEL ADJUSTABLE PENILE BANDS
External Constriction Device for Penile Rigidity

Submitter: Pacifico R. Burgos
ERECXEL Enterprises
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Los Angeles, CA 90065
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Contact Person: Same as Above

Date Originally Submitted: September 30, 1999

Trade Name: ERECXEL Adjustable Penile Bands

Common Name: External Device for Penile Rigidity

Equivalence is claimed to:

REJOYN Constriction Rings	POST-T-VAC, Inc.	K981180

CFR Number: Unclassified

Product Code: 78 LKY

Description of the Device:

ERECXEL Adjustable Penile Band is an external penile constriction device that is comprised of a split ring made of latex-free, bio-compatible rubberplastic. It is designed with fastening parts, consisting of interlocking teeth and cavities carried on each end of the ring. This simple mechanism permits the user to easily adjust the diameter of the device, allowing him to set its size to provide him the optimum degree of penile constriction that the device will effect during use.

The device is designed with a urethral groove to allow the normal ejaculation process to occur during its use. It is also provided with tabs on each fastening end to facilitate its quick release from the penile shaft and is available in different sizes to accommodate the wide variation of penile sizes among men.

Full product description, directions for its proper use and contraindication warnings are contained in the device labeling.

Indicated Uses of the Device:

The ERECXEL Adjustable Penile Bands are indicated as over-the-counter treatment for men with erection problem due to penile venous leakage. During erection, the ERECXEL Adjustable Penile Bands device helps to produce penile rigidity by constricting the penile veins around the base of the penis to restrict the flow of blood from leaving the penis.

Comparison to Predicate Devices

The ERECXEL Adjustable Penile Band is similarly indicated for use and application as the predicate device. It significantly differs in technological design as provided by its fastening/adjust-ment apparatus. This technological innovation of the device is designed to improve the efficacy, safety and comfort during its use.

The predicate device is a set of non-adjustable solid constriction rings. The ERECXEL Adjustable Penile Band has a simple fastening apparatus for easily changing its diameter to fit the user's penile size and to adjust the level of penile constriction that it effects during use.

The predicate device uses accessories to be set around the penile base and also require significant strength for the use for its release from the penile shaft. The simple fastening/adjustment apparatus of the ERECXEL Adjustable Penile Band, and the tabs on each of its fastening ends allow easy setting and quick release from the penile shaft with no need of any accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2000

Mr. Pacifico R. Burgos
General Manager
ERECXEL ENTERPRISES
3249 San Fernando Road
Los Angeles, CA 90065

Re: K993343
ERECXEL Adjustable Penile Bands
Dated: January 25, 2000
Received: January 27, 2000
Unclassified/Procode: 78 LKY

Dear Mr. Burgos:

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 legally marketed predicate 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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(K) Number : K993343

Device Name: ERECXEL Adjustable Penile Bands

Indications for Use:

The ERECXEL Adjustable Penile Bands are indicated as over-the-counter treatment for men with erection problem due to penile venous leakage. During erection, the ERECXEL Adjustable Penile Bands device helps to produce penile rigidity by constricting the penile veins around the base of the penis to restrict the flow of blood from leaving the penis.

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use_____ or Over-the-Counter Use ✓

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993343

(Optional Format 1-2-96)