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K990006

ERCONS, Inc.
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New York, NY, 10040
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510(k) SUMMARY
for ERCO-VAC ™ -C
External Penile Rigidity System

Submitter: Dr. Yakov Altshuler, Vice President

Date: Dec.23, 1998

Trade name - Erco-Vac ™ –C

Common name -external penile rigidity device

Equivalence is claimed to:

1. ErercAid	Osbon Medical Systems, Ltd.	K841257
2. VED	Mission Pharmacal Co.	K901223
3. Pos-T-Vac	POS-T-VAC	K960828
4. Erco-Vac ™	ERCONS, Inc.	K981357
Code of Federal Regulation (CFR) Number:		Unclassified
Product Code:		78 LKY

SECTION 514 SPECIAL CONTROLS

Special Controls under Section 514 of the Act have not been developed for these devices. Reference is made in later sections of this document to voluntary industry standards.

DEVICE DESCRIPTION

Intended Use

Erco-Vac ™ -C is used to create an erection in men with erectile dysfunction and for augmenting of male potency

Erco-Vac ™ -C can be used by patients with following conditions:

Diabetes

Venous leakage

Prostatectomy

Hypertension

Psychogenic condition

Impotence due to radiation therapy

Spinal cord injury

Structure features

Erco-Vac ™ -C is based on the same scientific concept as known marketable vacuum constriction devices. Vacuum applied to penis causes blood inflow, engorgement and state of erection. Constriction device preliminary installed on the edge of vacuum chamber is forced to slip off on the root of the penis. By hindering blood outflow, constriction device sustains erection and makes intercourse possible after removal of vacuum chamber.

Vacuum constriction treatment is now recognized as the first line remedy, preferable to other treatments of erection dysfunction - sex therapy, self injections, venous and arterial surgery, implantation of penile prosthesis. At the same time, known marketable devices have deficiencies and drawbacks which make them unacceptable to many potential users.

Erco-Vac ™ -C is an improved version of Erco-Vac ™ which was developed with the goal to overcome known deficiencies and limitations of vacuum constriction devices. Novelty elements, introduced into the system's structure are listed below:

1. Transferable air tight penile seal
2. Constriction device with controllable inward radial pressure
3. Cuff and quick release loop for convenient mounting of constriction device on the vacuum chamber and safe removal from the penis.
4. Automatic vacuum release
5. Transferring device
6. Vacuum chamber with a domed closed end, customised to the user's penile anatomy.

Comparison of technological characteristics

1. Air tight seal

Predicate devices:

The air tight seal is provided by pressing the open end of the vacuum chamber against the abdomen. To adjust to different penile sizes and to prevent scrotal tissue from sucking in, adapter inserts are needed.

Erco-Vac ™ -C:

Transferable air tight penile seal and baffle allow adjustment to different penile girth without additional inserts.

2. Constriction devices

Predicate devices:

Constriction device generally comprise rings of elastic rubber with C-shaped handles or tabs for removal from erect penis. To provide sufficient inward pressure, one or more of constriction rings with different durometer have to be placed at the edge of an open end of the vacuum chamber. Despite high cost due to a number of expensive molds, there is no way to provide smooth control of the inward pressure, which may happen to be excessive and cause discomfort, numbness, bruises.

Erco-Vac ™ -C:

Constriction device is an elastic ribbon wrapped with multiple turns (Erco-Ribbon ™ -C). The user may prearrange desirable inward pressure by changing the tension and number of turns during wrapping.

Other advanced features substantially improve performance of Erco-Vac ™ -C

3. Automatic vacuum release

During transfer of penile seal and constricting device the vacuum in the chamber releases automatically.

4. Transferring device provides easy slip off of the constriction device and transferable penile seal onto erect penis.

SUMMARY:

Erco-Vac ™ -C has the same intended use as Predicate devices.
Technological differences of Erco-Vac ™ -C provide superior performance. and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Yakov Altshuler, Ph.D.
Vice President
ERCONS, Inc.
66 Overlook Terrace, Suite 2E
New York, NY 10040

Re: K990006
Erco-Vac™ -C, Vacuum Erection Device
Dated: December 23, 1998
Received: January 4, 1999
Unclassified/Procode: 78 LKY

Dear Dr. Altshuler:

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) 594-4613. 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,

Capt. Daniel G. Schultz, M.D.
Acting 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 K990006

Device Name: Erco-Vac™-C

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Hypertension

Psychogenic condition

Impotence due to radiation therapy

Spinal cord injury

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use
(Per 21 CFR 801-109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990006