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ERCONS, Inc.
 66 Overlook Terrace, s-te 2E
 New York, NY 10040
 Tel. 1-212-927 3275
 Fax 1-212-927 7387

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510(k) SUMMARY
for
ERCO-RIBBON™
 Constriction Device for External Penile Rigidity System

Submitter: Dr. Yakov Altshuler, Vice President

Date: Apr. 7, 1998

Trade name - Erco-Ribbon™

Common name - constriction device for external penile rigidity system

Equivalence is claimed to:

ErecAid	Osbon Medical Systems, Ltd.	K841257
Revive	Revive System Corp.	K844445
Confidence	Performance, Inc.	K891125
VED	Mission Pharmacal Co.	K901223
VET	VET-CO, Inc.	K9022403.
Pos-T-Vac	POS-T-VAC	K960828
Code of Federal Regulation (CFR) Number:		Unclassified
Product Code:		78 LKY

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Intended Use

Erco-Ribbon™ is used to maintain penile rigidity in men with erectile dysfunction. It restricts blood outflow from the penis after the patient has obtained an erection (either with the aid of a vacuum pump or naturally).

Men with firm but short lasting erection may use constricting device separately.

If a man is impotent to a degree that he is unable to achieve a natural erection, a vacuum constriction system may help him to overcome this dysfunction.

Erco-Ribbon™ can be used for patients with following conditions:

- a) separately:
 - premature ejaculation,
 - firm but short lasting erection
- b) as a part of a vacuum constriction system:
 - Diabetes,
 - Venous leakage,
 - Prostatectomy,
 - Hypertension,
 - Psychogenic impotence,
 - Impotence due to radiation therapy,
 - Spinal cord injury.

DESCRIPTION

A constriction ribbon is made of elastic and soft rubber-like material with generally rectangular cross section. A belt with release loop is used for keeping the constrictor in a prearranged tightened position and for unlocking the ribbon.

The material conforms FDA regulation for devices contacting human skin.

For unlocking of the constrictor, the belt's release loop is pulled forward. The belt slips off, allowing easy unwrapping of the constricting ribbon.

A mounting tube comprises a segment of acrylic tube.

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For arrangement of Erco-Ribbon™ penile constriction device, the ribbon is wrapped with the tension by multiple turns over the segment of the proximal end of the mounting tube. (or a vacuum chamber, when Erco-Ribbon™ is used as a part of a vacuum constriction system).

SUBSTANTIAL EQUIVALENCY COMPARISON

Comparison of design and performance of marketable constriction rings and Erco-Ribbon is made with consideration of the impact of device's design on its safety and effectiveness. Considered marketable Predicate devices and Erco-Ribbon™ are constriction devices with the same intended use, but have different technological characteristics.

Predicate devices:

To provide sufficient inward pressure on erected penis, one or more of constriction rings have to be placed at the edge of an open end of the vacuum chamber. Rings are molded of natural or synthetic rubber with different durometer numbers, usually in the range of 30 to 60 and are manufactured in large, medium and small sizes. To provide acceptable inward pressure, selection for individual users is based on size, durometer and a number of constriction rings used together. Despite high cost due to a number of expensive molds, there is no way to provide smooth control of the pressure which happens to be excessive and causes discomfort, numbness, bruises.

Placement of rings presents certain technical difficulties. Recognizing this problem, special cone-shaped applicators are added to the system. Applicators facilitate the problem, but complicate the system and increase its cost.

Discomfort and pain may be caused by twisting of doubled rings during their transfer onto the penis and because of intertwining with pubic hair.

Removal of constriction ring from erected penis could be painful too, especially when two or more rings are used together. In this case after removal of the first ring the penis is still engorged, as the remaining ring prevents blood outflow.

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There are countless possibilities of providing proper pressure of the constricting device during fabrication: by selection of constricting ribbon's material, cross section, length.

With the constrictor of given properties and dimensions, the user may prearrange desirable pressure by changing the tension and number of turns during wrapping. The present design radically reduces major technical difficulties of constriction ring associated with its placement on the vacuum chamber. A multyturn constriction ribbon is much easier to apply than a solid constriction ring as the force necessary to extend multyturn constrictor is much lower than for solid ring.

SUMMARY:

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

Erco-Ribbon™ is substantially equivalent to constriction devices that have been marketed for many years.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Yakov Altshuler, Ph.D.
Vice President
Ergons, Inc.
66 Overlook Terrace, Suite 2E
New York, NY 10040Re: K981343
Erco - Ribbon™ - OTC
Dated: October 9, 1998
Received: October 13, 1998
Regulatory Class: Unclassified
Unclassified/Procode: LKY 78

Dear Dr. Altshuler:

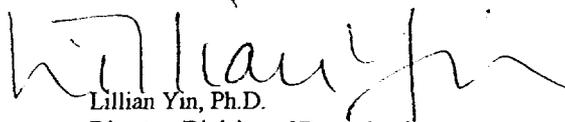
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 ~~K972353~~ K981343
Device Name: Erco-Ribbon™

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Indications for use:

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- Psychogenic impotence
- Impotence due to radiation therapy
- Spinal cord injury

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 8)


OR
Over-The-Counter Use

(Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K981343