

K974470
P1 of 1

Appendix C

**510(k) Summary
Encore, Inc.**

JAN - 9 1998

VTU-E™ Vacuum Erection System

I. General Information on Submitter:

Name: Encore, Inc.
Address: 2300 Plantside Drive, Louisville, KY 40299-1928
Telephone: (502) 499-1556
Fax: (502) 499-1840
Name of Contact Person: Mr. Boyd Bennett
Date Summary Prepared: November __, 1997

II. General Information on Device

Name: VTU-E™ Vacuum Erection System
Classification Name: External Penile Rigidity Device

III. Predicate Device: VTU-1™ (510(k) No. K971257)

IV. Description of the Device:

The VTU-E™ consists of four silicone rubber constriction rings and a plastic penile cylinder attached to a battery-powered vacuum pump. The penis is placed into the penile cylinder and the vacuum pump is used to reduce the air pressure within the cylinder and thus cause a penile erection. Once the penis is erect, the silicone rubber ring is placed around the base of the penis in order to maintain the erection.

V. Intended Use:

The VTU-E™ is intended to aid in the production and maintenance of a penile erection in individuals suffering from impotence.

VI. Technological Characteristics of Device Compared to Predicate Device:

The VTU-E™ and the VTU-1™ have identical technological characteristics with the exception of the type of vacuum pump used to reduce the air pressure within the penile cylinder. The VTU-1™ used a manually operated pump, while the VTU-E™ uses a battery-powered pump. Both pumps serve the same purpose and have similar performance characteristics.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 1998

ENCORE, Inc.
c/o Donald R. Stone
McKenna & Cuneo, L.L.P.
1900 K. Street, N.W.
Washington, DC 20006-1108

Re: K974470
VTU-E™ Vacuum Erection System
Dated: November 26, 1997
Received: November 26, 1997
Unclassified/Procode: 78 LKY

Dear Mr. Stone:

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

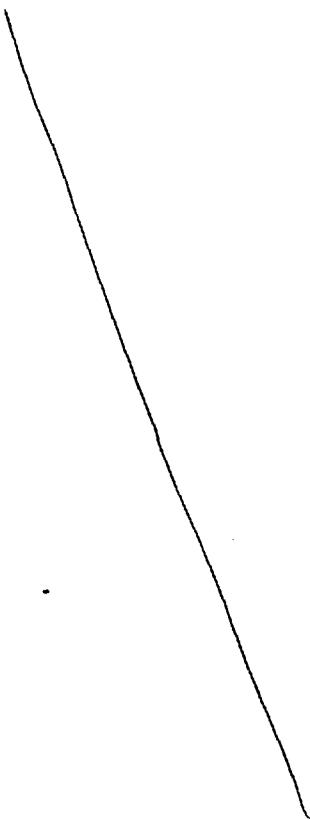
Enclosure

510(k) Number (if known): _____

Device Name: VTU-E Vacuum Erection System

Indications For Use:

The VTU-E is intended to aid in the production and maintenance of a penile erection in individuals suffering from impotence.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Sathig /
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974470

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use