K971443

P191

RAPPORT V.T.D.
510k SUBMISSION

SUMMARY

SEP 26 1997

Submitted by:

Robert E. Shaw
Owen Mumford, Inc.
849 Pickens Industrial Drive
Suite 14
Marietta, GA 30062-3165

Device Name: Rapport VTD
Substantial Equivalence: Osbon Erec-Aid
Classification Name: External Penile Rigidity Device

DESCRIPTION:

The Rapport Vacuum Therapy Device is an impotence management system providing men with erectile dysfunction to create and maintain an erection.

The device works on a vacuum principle, creating a negative pressure around the penis thus creating an erection.

The device construction is detailed in the section on PRODUCT DESCRIPTION.

INTENDED USE:

Intended to achieve a penile erection for males suffering from erectile dysfunction (See Section on INTENDED USE), the same as the substantially equivalent OSBON Erec-Aid.

OPERATIONAL:

The principle of operation and design concepts are substantially equivalent to the OSBON Erec-Aid.

PERFORMANCE:

The vacuum performance of the Rapport VTD is similar to the Osbon Erec-Aid (as detailed in Section 6). The device is safe and effective when used as directed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 1997

Mr. Robert E. Shaw
Vice President
Owen Mumford, Inc.
849 Pickens Industrial Drive, Suite 14
Marietta, Georgia 30062-3165

Re: K971443
Rapport V.T.D.
Dated: July 28, 1997
Received: July 30, 1997
Regulatory class: unclassified
Product code: 78 LKY

Dear Mr. Shaw:

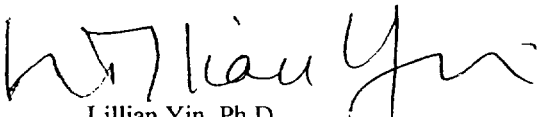
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K9714433

Device Name: Rapport V.T.D.

Indications For Use:

Intended to achieve a penile erection for males suffering from erectile dysfunction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971443

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)