K982275

DEC 4 1998

510(k) SUMMARY
RAPPORT V.T.D.
OVER THE COUNTER SALES

APPLICANTS ADDRESS:	Owen Mumford Inc 849 Pickens Industrial Drive Suite 14 Marietta GA 30062 USA
CONTACT:	Mr Robert Shaw
POSITION:	Director
TEL:	770 425 5138
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REGISTRATION No:	1058602
TRADE NAME	RAPPORT V.T.DD.
COMMON NAME:	VACUUM THEARAPY PUMP
CLASSIFICATION NAME:	EXTERNAL PENILE RIGIDITY DEVICE.
CLASS:	UNCLASSIFIED
CLASSIFICTION PANEL:	GASTROENTEROLOGY & UROLOGY
PANEL CODE:	78 LKY
CFR NUMBER:	Not allocated
MANUFACTURER:	Owen Mumford Limited Brook Hill Woodstock Oxfordshire OX20 1TU United Kingdom
REGISTRATION No:	8021764
DATE PREPARED:	24th September 1998

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SUBTSANTIAL EQUIVALENCE

This product is identical, with the exception of the labelling, to the Owen Mumford Rapport V.T.D. for which 510(k) K971443 was issued on 26th September 1997.

DEVICE DESCRIPTION

The Rapport VTD is a vacuum therapy impotence management system providing a simple, non-surgical, non-invasive method of creating and maintaining an erection in men with erectile dysfunction.

The product consists of a hand pump and penile tube, used to create a vacuum, and loading cones, constriction rings and transfer sleeve used to maintain the erection.

INTENDED USE

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

TECHNICAL COMPARRISON

The VTD for over the counter sales is technically identical to the device to which substantial equivalence is claimed.

NON-CLINICAL TRIAL DATA & CONCLUSIONS

No additional trial data has been generated for the over the counter version of the product as data supplied in the original 510(k) K971443 is considered adequate. The data showed that the device provided an answer to the impotence problems in over 80% of the men used in study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

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

Re: K982275
Rapport V.T.D.-OTC
Dated: October 16, 1998
Received: October 19, 1998
Regulatory Class: Unclassified
Procode: 78 LKY

Dear Mr. Robert 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 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 : K982275/S1

Device Name: **Rapport VTD**

Indications For Use

Intended to achieve a penile erection for men suffering from erectile dysfunction

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982275/S001