NOV 25 1998

K983045

510k SUBMISSION

AMIELLE VAGINAL DILATOR

SUMMARY

Submitted by:

Mr. S D Miles
Head of Regulatory Affairs
Owen Mumford Limited
Brook Hill
Woodstock
Oxfordshire
OX7 1TU

Device Name:	**Amielle**
Substantial Equivalence:	**Young's Vaginal Dilator**
Classification Name:	**Vaginal Stent**

Owen Mumford have been marketing Amielle throughout Europe for over 3 years without any adverse customer reports. The product has been widely accepted as an excellent product for treatment of Vaginismus and Dyspareunia.

DESCRIPTION

Four smooth, high polished finish, hollow, penile shaped cones which are graduated in size and length. Owen Mumfords Amielle is visually and mechanically similar to that of Young's Vaginal Dilator to which substantially equivalence is claimed.

INTENDED USE

Both Amielle and Young's Dilators are intended for the treatment of Vaginismus and Dyspareunia. The concept is gradual dilation of the vagina until the problem is under control.

OPERATIONAL

The principle and design concepts and application of Amielle and Young's Vaginal Dilators are substantially equivalent.

PERFORMANCE

Performance of both systems are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

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

Re: K983045
Vaginal Dilator
Dated: August 31, 1998
Received: September 1, 1998
Regulatory Class: II
21 CFR 884.3900/Procode: 85 KXP

Dear Mr. Robert E. Shaw:

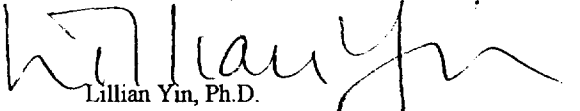
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (if known): n/k K983045

Device Name: AMIELLE.

Indications for Use:

The device is intended to treat women suffering from vaginismus and dyspareunia. VAGINISMUS is the involuntary spasm of the muscles in the vaginal wall which then inhibits sexual intercourse by making it painful or impossible. DYSPAREUNIA is the pain experienced during sexual intercourse caused by physical and/or emotional problems.

The device comes in varying sizes, the most appropriate is then selected by the physician for use by the patient and the patient's partner as an assistant if appropriate. It is used as a tool to DILATE the vagina in controlled stages.

The device can be autoclaved or sterilised by normal methods.

Concurrence of CDRH, Office of Device Evaluation (ODE).

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983045