K990593

MAY 24 1999

510(k) SUMMARY
PelvX Incontinence Dish

DesChutes Medical Products, Inc.
1011 SW Emkay Drive, Suite 104
Bend, OR 97702
Date Prepared: 2/19/99

1. CONTACT PERSON

Denise Bestwick
Phone : (541) 385-0350
Fax : (541) 382-2079

2. NAME OF THE MEDICAL DEVICE

Classification name : Vaginal Pessary
Common/usual name : Vaginal Pessary
Proprietary name : PelvX Incontinence Dish

3. DEVICE CLASSIFICATION

PelvX Incontinence Dish Vaginal Pessary is classified by the FDA under the heading of Vaginal Pessary (21 CFR Section 884.3575) as a Class II device with Product Code: 85HHW.

4. STATEMENT OF SUBSTANTIAL EQUIVALENCE

PelvX Incontinence Dish Vaginal Pessary is substantially equivalent to the Milex Incontinence Dish pessary, manufactured by Milex Products, Inc., Chicago, IL 60631.

A comparison of the PelvX Devices versus the Milex Devices is presented in Tables 1 and 2.

5. INTENDED USE

The PelvX Incontinence Dish Vaginal Pessary is intended for treatment of stress urinary incontinence combined with a mild 1st or 2nd degree uterine prolapse and/or a mild cystocele.

6. DESCRIPTION OF DEVICE

The PelvX Incontinence Dish Vaginal Pessary is a pessary intended for the treatment of stress urinary incontinence. It is made of medical grade silicone and is shaped like a dish to surround and support the cervical area and bladder areas. Holes in the dish allow drainage of vaginal fluids. It features a bulbous portion at one location on its circumference designed to support and elevate the bladder neck, thereby providing improved urethral sphincter control. Figure 1 shows a diagram of the PelvX Incontinence Dish.

7. SUBSTANTIAL EQUIVALENCE COMPARISON

Tables 1 and 2 demonstrate the relative regulatory classifications and features of the DesChutes Incontinence Ring compared to the Milex Incontinence Ring.

The common and classification names for these products are identical. In addition, both of these devices are prescription devices.

These vaginal pessaries are reusable devices which must be fitted, checked for continuing fit, and monitored for developing problems by medical personnel. The DesChutes and Milex Dishes have identical intended uses. The contraindications for their use are also the same. The pessaries are supplied clean but not sterile. Cleaning procedures are also the same. Both devices come in a variety of sizes for fitting.

There are several differences between the DesChutes and Milex products. First, DesChutes explicitly states that these are single patient devices while Milex is silent on this point. Second, DesChutes adds a precaution that the pessary should be removed before coitus. Finally the pessaries are packaged differently which does not affect the intended use or performance of the product.

Table 1—Comparison of Regulatory Classifications

Category	DesChutes Medical Products PelvX Incontinence Dish	Milex Products Incontinence Dish with Support
Common or usual name	vaginal pessary	vaginal pessary
Classification name Product Code	884.3575 Vaginal pessary 85HHW	884.3575 Vaginal pessary 85HHW
Prescription device	Yes	yes

Table 2 —Comparison of Device Features

Feature	DesChutes Medical Products PelvX Incontinence Dish	Milex Products Incontinence Dish with Support
Intended Use	treatment of stress urinary incontinence combined with 1st or 2nd degree prolapse and/or a mild cystocele	stress urinary incontinence coupled with a mild 1st or 2nd degree prolapse and/or a mild cystocele
Single patient device	yes	implied but not specifically stated
Single use or reusable	reusable	reusable
Must be initially fitted by medical personnel	yes	yes
Requires regular visits to medical personnel for checking	yes	yes
Contraindications	1) pelvic infections or lacerations 2) non-compliant patients 3) endometriosis 4) pregnancy	1) pelvic infections or lacerations 2) non-compliant patients 3) endometriosis 4) pregnancy
Cautions	1) pessary should be removed before coitus	
Sterilization status	clean, but not sterile	clean, but not sterile
Foldable	yes	yes
Maintenance	clean with warm water and soap when removed	clean with water and mild soap when removed
Material Outer	medical grade silicone	medical grade silicone
Color additives	yes	yes
Number of models	6	6
Sizes	2.25", 2.5", 2.75", 3", 3.25, 3.5"	55mm, 60mm, 65mm, 70mm, 75mm, 80mm, 85mm
Instructions	physician and patient instructions	physician/nurse and patient instructions
Packaging	plastic bag inside paperboard box with label	plastic clamshell with instructions for use visible

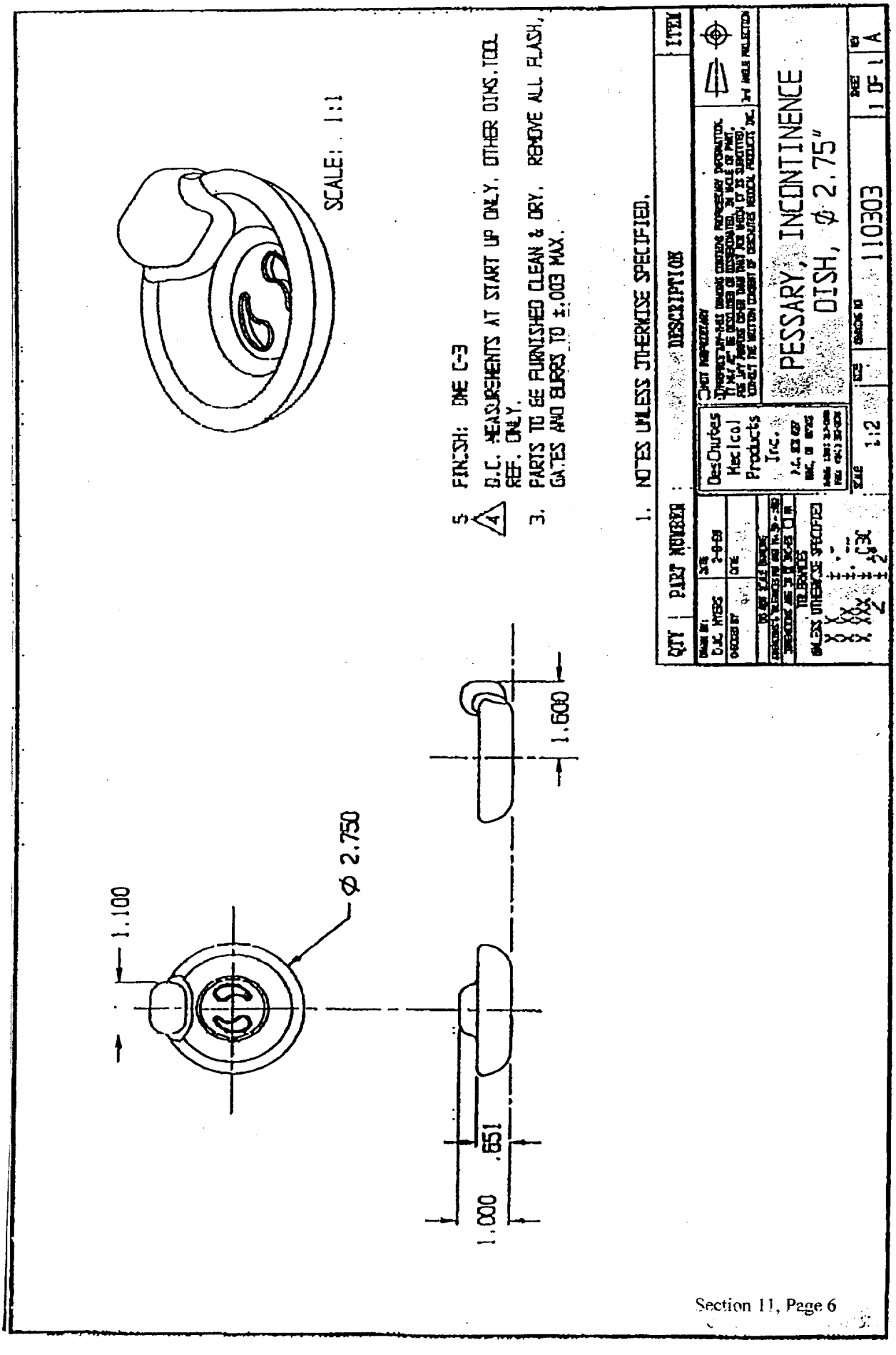
8. SUMMARY OF SAFETY TESTING

The DesChutes PelvX Incontinence Dish is made of a known medical grade silicone. Extensive testing of this silicone was performed for DesChutes Medical Products by NamSA. The following tests were performed:

Acute Systemic Toxicity
Cytotoxicity
Muscle Implantation (1 week)
Muscle Implantation (4 weeks)
Muscle Implantation (12 weeks)
ISO Sensitization Study
Pyrogenicity
Vaginal Irritation (14 days)

The material used is the same as for the DesChutes Donut Pessary (510(k) #974117). This testing regime was compared to requirements in "General Purpose Memorandum G95-1 Use of International Standard ISO-10993" for devices in contact with mucosal membranes for between 24 hours and 30 days. The test results support the position that this material is substantially equivalent to the other materials used for similar purposes.

FIGURE 1. DIAGRAM OF PELVX INCONTINENCE DISH



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 1999

Ms. Denise Bestwick
Director, Quality Assurance and
Regulatory Affairs
DesChutes Medical Products, Inc.
1011 S.W. Emkay Drive, Suite 104
Bend, OR 97702

Re: K990593
PelvX Incontinence Dish Vaginal Pessary
Dated: February 22, 1999
Received: February 24,1999
Regulatory Class: II
21 CFR §884.3575/Procode: 85 HHW

Dear Ms. Bestwick:

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 legally marketed predicate 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(K) Number (if known): K990593

Device name: PelvX Incontinence Dish Vaginal Pessary

Indications for Use:

The PelvX Incontinence Dish Vaginal Pessary is a vaginal pessary intended for the treatment of stress urinary incontinence combined with mild 1st or 2nd degree uterine prolapse and/or a mild cystocele.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Degnan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990593

Prescription Use ✓ OR Over-The-Counter Use _____