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K994079

DesChutes Medical Products, Inc.

CONFIDENTIAL

ReFlex 510(k)

SECTION 5 – 510(k) SUMMARY**510(k) SUMMARY****THE REFLEX TREATMENT SYSTEM**

DesChutes Medical Products, Inc.
1011 SW Emkay Drive, Suite 104
Bend, OR 97702
Date Prepared: December 2, 1999

1. CONTACT PERSON

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

2. NAME OF THE MEDICAL DEVICE

Proprietary name : THE REFLEX TREATMENT SYSTEM
Classification name : PERINEOMETER
Common/usual name : PELVIC MUSCLE EXERCISER

3. DEVICE CLASSIFICATION

The ReFlex System is classified by the FDA under the heading of Perineometer (21 CFR Section 884.1425) as a Class II device with Product Code: 85HIR.

4. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The ReFlex Treatment System is substantially equivalent to the DesChutes Medical Products' PeriPump Pelvic Muscle Exercise Biofeedback device (510(k) K934552).

A comparison of The ReFlex Treatment System versus The PeriPump is presented in Tables 5.1 and 5.2.

5. DESCRIPTION OF DEVICE

The ReFlex Treatment System is a comprehensive, behaviorally-based program designed for independent use by incontinent people in their own home. The product kit includes a personal training device, an informational video, instructional journal, and direct clinical support via phone and internet. At the program's core is the pneumatically-based ReFlex Trainer, a handheld device which when connected to the vaginal sensor displays the magnitude of pelvic muscle contractions.

6. INTENDED USE/INDICATIONS

The ReFlex Treatment System is intended for the treatment of stress incontinence and/or urge incontinence in females.

7. SUBSTANTIAL EQUIVALENCE COMPARISON

Tables 5.1 and 5.2 demonstrate the relative regulatory classifications and technological characteristics of the two devices.

Table 5.1 Comparison of Regulatory Classifications

Category	DesChutes Medical Products' ReFlex Treatment System	DesChutes Medical Products' PeriPump (K934552)
Common or usual name	Pelvic muscle exerciser	Pelvic muscle exerciser
Classification name	884.1425 Perineometer	884.1425 Perineometer
Product Code	85HIR	85HIR
Intended Use/Indications	Treatment of stress incontinence and/or urge incontinence in females	Treatment of stress incontinence and/or urge incontinence in males and females
Prescription device	No	Yes

Table 5.2 Comparison of Device Technological Characteristics

Feature	DesChutes Medical Products OTC ReFlex	DesChutes Medical Products PeriPump (K934552)
Target population	Women with mild incontinence	Women and men with mild incontinence
Single patient device	Yes	Yes
Single use or reusable?	Reusable	Reusable
Requires regular visits to medical personnel	No	No
Sterilization status	Clean, but not sterile	Clean, but not sterile
Biofeedback display information	LCD displays magnitude of pelvic muscle contractions	LED displays magnitude of pelvic muscle contractions
Performance	Clinical Study; Balloon Volume-to-Burst Testing	Performance Testing – Simulated Use; Balloon Volume-to-Burst Testing

Material - Sensor	Medical grade silicone (polydimethylsiloxane)	Medical grade silicone (polydimethylsiloxane)
Color additives	None	None
Biocompatibility	Balloon sensor testing exceeds guidelines set forth in ISO 10993. Testing results indicate material is biocompatible, non-toxic and well-tolerated by mucosal membranes.	Balloon sensor testing exceeds guidelines set forth in ISO 10993. Testing results indicate material is biocompatible, non-toxic and well-tolerated by mucosal membranes.
Chemical Safety	Addressed by biocompatibility testing (ISO 10993)	Addressed by biocompatibility testing (ISO 10993)
Number of models	One (female)	Two (male/female)
Anatomical Sites	Vagina	Vagina (female), rectum (male)
Instructions	Patient instructions for home use -- The ReFlex Journal	Patient instructions for home use -- User Guide
Energy Used and/or Delivered	Energy supplied by 3 AAA replaceable batteries	Energy supplied by 2 AA replaceable batteries
Standards met	ISO 10993; UL2601-1, 2 nd Edition and EN 60601-1-2:1993	ISO 10993; UL 544, 3 rd Edition
Electrical safety	UL2601-1, 2 nd Edition, EN 60601-1-2:1993	UL 544, 3 rd Edition
Packaging	Sensors inside plastic bag; trainer, sensors and journal inside cardboard box	Sensors inside plastic bag; trainer, sensors and journal inside cardboard box

8. SUMMARY OF SAFETY AND EFFICACY TESTING

A. Non-Clinical Performance Data (In-Vitro and Electrical Testing)

The ReFlex Treatment System was designed and tested to meet the following standards: ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing; Emissions and Immunity Testing (EN60601-1-2:1993); Medical Electrical Equipment, Part 1: General Requirements for Safety (UL 2601-1, 2nd Edition).

Extensive biocompatibility and safety testing of the silicone material used in the balloon sensors was performed for DesChutes Medical Products by NamSA. The following tests were performed:

Cytotoxicity Study Using the ISO Elution Method
 ISO Sensitization Study in the Guinea Pig (Maximization Method)
 Vaginal Irritation Study in the Rabbit with Histopathology - 14 Days
 Acute Systemic Toxicity Study in the Mouse (Extract)
 Rabbit Pyrogen Study (Material Mediated)
 ISO Muscle Implantation Study in the Rabbit with Histopathology (1 week)

ISO Muscle Implantation Study in the Rabbit with Histopathology (4 weeks)

ISO Muscle Implantation Study in the Rabbit with Histopathology (12 weeks)

This testing regime was compared to requirements in "General Purpose Memorandum G95-1 Use of International Standard ISO-10993." The test results from all tests support the position that this material is substantially equivalent to the material used in the predicate device and indicate that the material is biocompatible, non-toxic and well tolerated by mucosal membranes.

B. Clinical Performance Data

The ReFlex Treatment System has been extensively tested for its safety and efficacy in alleviating symptoms of stress and/or urge incontinence. In addition, clinical testing of the product demonstrated that the device can be used outside the supervision of a licensed practitioner, and adequate directions for use have been prepared.

The conclusive data from this clinical study demonstrated that self-selected healthy women of a wide age-range with symptoms of urge and/or stress incontinence can improve their symptoms and lower their severity index with a minimal intervention, comprehensive, self-directed home biofeedback continence system. All study participants who completed the study saw some degree of symptom improvement. A remarkable 43% of participants were completely cured of their symptoms of incontinence. Another 36% had over 50% improvement of their symptoms for an overall improvement rate of 79%.

9. CONCLUSION

The ReFlex Treatment System has been shown to be safe and efficacious for its intended use through extensive biocompatibility testing of the material that comes into contact with the mucosal membranes, the study conducted to demonstrate the efficacy of the self-directed instructions and the resulting data demonstrating that all study participants who completed the 16 week program realized some degree of improvement of their incontinent symptoms.



MAR 1 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Denise Bestwick
Director, Regulatory Affairs
DesChutes Medical Products, Inc.
1011 SW Emkay Drive, Suite 104
Bend, OR 97702

Re: K994079
The ReFlex Treatment System (for Females)
Regulatory Class: II
Dated: December 2, 1999
Received: December 2, 1999
21 CFR §884.1425/Procode: 85 HIR

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION 4 – STATEMENT OF INDICATIONS FOR USE

Statement of Indications for Use

Applicant: DesChutes Medical Products, Inc.

510(K) Number (if known): K994079

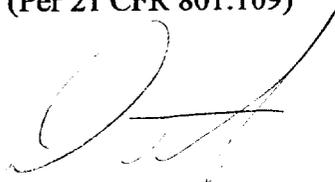
Device name: The ReFlex Treatment System

Indications for Use:

The ReFlex Treatment System is intended for the treatment of stress incontinence and/or urge incontinence in females.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)



Prescription Use _____

OR

Over-The-Counter Use _____