

NOV 20 1998

K98/277



510(k) Summary

Summary of Safety and Effectiveness

Periform® Perineometric Probe and Pelvic Floor Contraction Indicator

Manufactured by:

NEEN HealthCare
Old Pharmacy Yard, Church Street
Dereham, Norfolk NR19 1DJ
England, United Kingdom.

Sold by:

Verimed International, Inc.
11950 NW 39 St., Suite D
Coral Springs, FL 33065 {USA}

Telephone: (954) 344-2454
Fax: (954) 340-8812

Contact Person:

A handwritten signature in black ink, appearing to read "K. Puppala", is written over a horizontal line.

Kishore Puppala,
Product Manager,
Verimed International, Inc.

April 2, 1998.

Date Submitted

Name of Device

Trade Name: Periform®

Common name: Perineometric Probe

Classification: Perineometer (per 21 CFR section 884.1425)

Identification of Predicate Device

Verimed contends that the Periform® probe is substantially equivalent to the Verimed Electromyographic Perineometer™ [510(k) number K913912] and the PerryVaginal™ Sensor (also known as the PerryMeter Vaginal Perineometer) [510(k) number K911190].

Description of Device

The Periform® is a vaginal perineometric probe designed specifically for the acquisition of the naturally present superficial EMG signals of the human vaginal wall. Surface electromyography (sEMG) is the technique of measuring and filtering the electrical impulse (action potential) signals generated by muscle fibers during contraction. The probe conducts these signals to a biofeedback device for further processing. The anatomy of the pelvic floor presents a difficulty in obtaining these signals. The use of a perineometric probe overcomes this difficulty.

The purpose of the Periform® is to improve the voluntary control and strength of the pelvic floor muscles with the aid of biofeedback equipment.

Intended Uses**Indications**

- ◆ Treatment of stress, urge, and mixed incontinence.
- ◆ Sensor for SEMG behavioral training.
- ◆ Facilitation in identification of the pubococcygeus muscles.
- ◆ Strengthening of the pelvic floor muscles through biofeedback-assisted pelvic floor exercises.
- ◆ Qualitative evaluation of the pelvic floor musculature using the Pelvic Floor Contraction Indicator.

Contraindications/ DO NOT USE

- ◆ Do not use during the menstrual period or when pregnant.
- ◆ Do not use if symptoms of a bladder infection are present.
- ◆ Do not use if symptoms of a vaginal infection are present.
- ◆ Do not use if patient has a history of urinary retention or symptoms thereof.
- ◆ Do not use with patients who have diminished mental capacity or physical competence or who cannot handle the device properly.
- ◆ Do not use while pregnant or while attempting to become pregnant.

- ◆ Do not use if patient has an anatomical vaginal morphology and/or structure that does not permit proper insertion of the probe.
- ◆ Do not use this device in conjunction with electrical muscle stimulation.
- ◆ Do not use if patient is unable or unwilling to use device as directed and indicated.

Device Comparison

	Periform®	Verimed Electromyographic Perineometer™	PerryVaginal™ Sensor
510(k) number	--	K913912	K911190
Mode of Use	Reusable for a single patient	Same.	Same.
Parameter monitored	aggregate surface electromyogram	Same.	Same.
User feedback	None	None	None
Intended Use	To produce biofeedback signals for processing by an external biofeedback device.	Same.	Same.
Indications for Use	Treatment of stress and urge incontinence and facilitation of pelvic floor exercises.	Same.	Treatment of stress, urge, and mixed incontinence.
Performance Standards	Currently no performance standards exist for sEMG biofeedback perineometric probes.		
Target Population	Adult female urinary incontinence patients.	Same.	Same.
Anatomical Sites designated for use.	Female pubococcygeus muscle area.	Same.	Same.
Energy used and/ or delivered.	No energy delivered or used, only transported.	Same.	Same.
Compatibility with environment and other devices	Probe is not known to conflict with other devices or cause environmental hazards.	Same.	Same.
Where used	Hospitals, Clinics, Doctor's offices, or home use under clinician's supervision.	Same.	Same.
Sterility	Probe does not need to be sterile. Appropriate cleaning procedure included instructions for use.	Same.	Same.
# of Electrode Contacts	2	2	3
# of Lead Cables	2	2	1
Transducers	None	None	None
Body Material	High Impact Polystyrene, type 564	Plastic: Cycolac ABS-GPM-5600-4500-FGE	N/A
Biocompatibility of Body Material	Biocompatible	Biocompatible	Biocompatible

Pelvic Floor Contraction Indicator (PFCI) included?	Yes.	No.	No.
PFCI Tip and End Material	High Impact Polystyrene 564	N/A	N/A
PFCI Shaft Material	'Stamylan' low density polyethylene grade 2100 TNOO		
Electrode Material	Medical Grade Stainless Steel type 316S31	Series 300 Passivated Stainless Steel	Series 300 Passivated Stainless Steel
Biocompatibility of Electrode Material	Biocompatible	Biocompatible	Biocompatible
Electrode Orientation	Longitudinal	Circumferential	Longitudinal
Construction	2-piece mold	3-piece mold	3-piece mold
Sensing Method	sEMG biofeedback recording	Same.	Same.
Feedback Modes	No direct feedback to user	Same.	Same.
Electrical Safety	Device is passive: Not electrically powered	Same.	Same.
Electrodes and Conductive Media	Not applicable.	Not applicable.	Not applicable.
Intentional Electrical Current	Warning included in Instructions for Use. Socket type prevents easy intentional connection to AC source.	Warning included in Instructions for Use.	Warning included in Instructions for Use.
Unintentional Electrical Current	Probe is to be used with appropriate biofeedback device as stated in Basic Design Description, or with PFCI only.	Probe is to be used with biofeedback devices satisfying criteria listed in Basic Design Description.	Probe is to be used with biofeedback devices satisfying criteria listed in Basic Design Description.
Risk of Mechanical Injury	Risk prevention considered in design process (Attached).	Risk prevention considered in design process (Attached).	Unknown.
Risk of thermal or Radiation Injury	None: probe does not direct any form of electromagnetic energy or heat.	Same.	Same.
Chemical Safety	Body and electrodes constructed of chemically inert materials.	Same.	Same.
Shaft Length	76 mm	81 mm	55.9 mm
Shaft Diameter	Not applicable (N/A)	19.1 mm	17.8 mm
Probe Width	34 mm	N/A	N/A
Basal Bulb Diameter (Comparable to Periform's Flange Diameter)	N/A	63.5 mm	43.2 mm
Flange Diameter	28.2 mm	N/A	N/A
Terminal Bulb Diameter	N/A	31.8 mm	33.0 mm
Terminal Bulb Length	N/A	22.7 mm	26.7 mm
Electrode Spacing Distance	N/A	9.5 mm	11.4 mm
Spacing Type	Axial Incremental	Radial Incremental	Axial Incremental

Electrode Surface Area	4.9 cm ² x 2	7.5 cm ² x 2	1.2 cm ² x 3
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Non-Clinical Performance Data

An impedance test was performed to demonstrate that the Periform® is capable of transporting electrical signals with minimal attenuation. Various frequencies were used in order to verify that the Periform® would be effective in the range of frequencies encountered in pelvic floor biofeedback (typically less than 200 Hz). The test shows that the Periform® exhibits the low impedance values (around 10 ohms at all tested frequencies) needed for accurate recording of pelvic floor muscle activity.

Biocompatibility Testing

The materials used in the Periform® have undergone safety tests and were found to be safe according to the required standards for each test. Tests performed and results were as follows:

MATERIAL	TEST PERFORMED	RESULTS
Polystyrene type 564. Used in Periform® body.	USP tests for Class VI plastics (Systemic Injection, Intracutaneous Toxicity, Implantation Test)	Meets the requirements of USP Class VI Plastic
Medical Grade Stainless Steel 316S31. Used for Periform® electrodes.	Standard Item used in the manufacture of medical device to contact human tissue for transient periods (less than 2 hours)	Nontoxic.
Polythene. Used in Pelvic Floor Contraction Indicator. Not in contact with patient.	No test performed as this portion is not intended to contact the body.	N/A

Conclusion

The Periform® is safe and effective for its intended use and is substantially equivalent to its predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Kishore Puppala
Product Manger
Verimed International, Inc.
11950 N.W. 39th Street, Suite D
Coral Springs, Florida 33065Re: K981277
Periform® Perineometric Probe
Dated: August 28, 1998
Received: August 31, 1998
Regulatory Class: II
21 CFR884.1425/Procode: 85 HIR

Dear Mr. Puppala:

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 (Pre-market 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): K981277

Device Name: Periform® Perineometric Probe

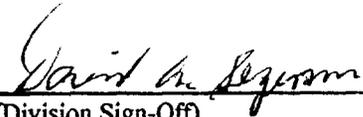
Indications For Use:

Biofeedback/monitoring vaginal probe intended for:

- Treatment of stress, urge, and mixed incontinence.
- Facilitation in identification of the pubococcygeus muscles.
- Strengthening of the pelvic floor muscles through biofeedback-assisted pelvic floor exercises.

(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 K981277

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)