

Model PS-1
Peña Muscle Stimulator
510(k)

APR - 3 1998

K980448

Appendix A: Summary of Safety and Effectiveness

General Information

Classification:	Class II
Common Name:	Muscle Stimulator
Device Trade Name:	Model PS-1 Peña Muscle Stimulator
Intended Uses:	Used to identify striated muscle in the treatment of high and low anorectal malformations
Predicate Devices:	Radionics Model 433-A General Hospital Stimulator P.B. Services Model A-200
Establishment Name and Address:	Radionics, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone	Nichole Riek, (781) 272-1233 ext. 274
Establishment Registration Number:	1222895
Performance Standards:	None established under Section 514

Substantial Equivalence Determination

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

Safety Summary

The system and unit testing results provided in this premarket notification verify that the Model PS-1 Peña Muscle Stimulator is safe and reliable. Audio indicators inform the user that the unit is properly functioning. In addition, a battery test function allows the user to check the batteries prior to use.

General Safety and Effectiveness Concerns

The device labeling contains Instructions for Use which include indications for use, cautions and warnings as well as the general operating instructions required for proper use of the device. This information promotes safe and effective use of the device.

Description of the Device and Basis for Substantial Equivalence

The PS-1 Peña Muscle Stimulator, addressed in this premarket notification, has the same technological characteristics as the commercially available Radionics Model 433-A General Hospital Stimulator and the P. B. Services Model A-200 Constant Current Peripheral Nerve Stimulator. Like these devices, the PS-1 is intended to be used as a stimulator.

Radionics' opinion with regards to substantial equivalence is based on the fact that the PS-1 complies with the same or equivalent requirements or standards as the above predicate devices. The design of the stimulating circuitry raises no new safety or effectiveness concerns. Radionics believes that the information and testing provided in this premarket notification clearly describe the PS-1 Peña Muscle Stimulator and demonstrate that it is as safe and effective as the aforementioned predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1998

Ms. Nichole Riek
Regulatory Associate
Radionics, Inc.
P.O. Box 438
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K980448
Model PS-1 Peña Muscle Stimulator
Regulatory Class: II
Product Code: IPF
Dated: February 3, 1998
Received: February 5, 1998

Dear Ms. Riek:

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.

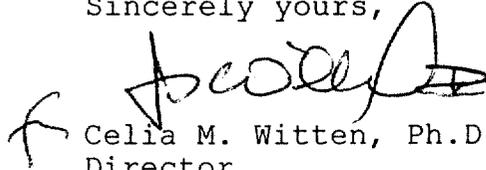
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A ~~substantially equivalent determination assumes compliance with~~ the current Good Manufacturing Practice requirement, 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.

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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) 594-4659. 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/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Model PS-1
Peña Muscle Stimulator
510(k)

Section II: Indications for Use

Indications for Use:

The PS-1 is indicated for use as an adjunct in the treatment of high and low anorectal malformations by helping in the identification of the striated muscles to be used in anal reconstructions.

Prescription Use _____
(Per 21 CFR 801.109)

X

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number 12930448