

Executive Summary:

The Gereonics, Inc. Ultra-Piezo Respiratory Effort Sensor is a device intended to be used in Sleep Disorders Testing for monitoring or recording abdominal (stomach) and thorax (chest) respiratory effort. It consists of a piezo sensor that converts breathing motion into an electrical output. The output goes into a passive low pass (15 Hz) electronic filter before the signal is then connected to a physiological recorder where the signal is amplified for monitoring or recording. This device is **not** intended for use as an Apnea Alarm.

The sensor is secured to the body using a one inch wide strap system of Velcro hook and elastic loop material. See Figure 1-2. The sensor is usable with adults, children and babies since various length straps are available to suit the body size needs.

This device is very similar to a respiratory effort sensor manufactured and sold by Pro-Tech, Inc., Woodinville, Washington. The essential differences are the strap width and the location of the passive electronic filter.

Intended Use:

The Gereonics Ultra-Piezo Respiratory Sensor is intended for use in sleep disorders studies to measure respiratory effort for monitoring or recording on a physiological recording system.

Description of Gereonics Ultra-Piezo Respiratory Effort Sensor:

The Gereonics Ultra-Piezo Respiratory Effort Sensor is intended for use in Sleep Disorders Testing for the measurement of respiratory effort and frequency. It is designed for use with a bioamplifier attached to a physiological recording system.

The Respiratory Effort Strap Sensor utilizes a processed polyvinylidene fluoride plastic film sensor as the detector for breathing motion. The small breathing deflection of the human body, typically measured on the stomach (abdomen) or chest (thorax), creates a small voltage in the piezoelectric plastic film sensor. There is no external voltage supply -- the sensor stressed by inhalation and exhalation directly converts motion to voltage.

A passive low pass electronic filter is connected directly to the sensor and filters out frequencies above 15 Hertz to minimize noise and allow breathing frequencies to be monitored.

The output from the passive filter, typically +/- 200 to 300 microvolts at 0.1 Hz, is connected to a bioamplifier in the physiological recording system where the signal is amplified for monitoring or recording.

Substantial Equivalence to Devices Already in Commercial Distribution:

The Gereonics Ultra-Piezo Respiratory Effort Sensor (Strap System) is similar in design, composition and function to at least two devices currently on the market.

1. The system is most similar to a device manufactured and sold by Pro-Tech, Inc. The 510(k) Number is K923402, Decision Date 12/30/92.
2. Another firm marketing a similar product is:
 EPMS, Inc.
 5212 Highberry Woods Road
 Midlothian, Virginia 23112
 The 510(k) Number is K903300, Decision Date 12/28/90.

Identification of Substantially Equivalent Device:

Device Name: Crystal Trace Respiratory Effort Sensor
 Manufacturer: Pro-Tech, Inc.
 P.O. Box 2165
 17710 134th Avenue N.E.
 Woodinville, WA 98072
 510(k) Number: K923402

Table of Comparison to a Legally Marketed Device:

<u>Features</u>	<u>Gereonics</u>	<u>Pro-Tech</u>
Velcro hook and loop elastic straps	Yes	Yes
Various strap sizes for adult and pediatric use	Yes	Yes
Plastic film piezo sensor	Yes	Yes
Built-in passive electronic filter	Yes	Yes
	(at sensor)	(molded in cable)
Termination of about 8 foot cable with DIN 45-802 Safety Connectors	Yes	Yes
Connects to physiological recording system	Yes	Yes
Comparable voltage output	Yes	Yes
Completely passive system		
No batteries or power supply	Yes	Yes
Velcro, Inc. strap width	1 inch	1.5 inches
Materials in contact with body	Velcro loop	Velcro loop & elastic



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 1999

Mr. Gerald Rost
Gereonics, Inc.
4650-143 Dulin Road
Fallbrook, CA 92028

Re: K983449
Gereonics Ultra-Piezo Respiratory Effort Sensor
Regulatory Class: II (two)
Product Code: 73 BZQ
Dated: January 22, 1999
Received: January 25, 1999

Dear Mr. Rost:

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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement:

510(k) Number: K983449

Device Name: Ultra-Piezo Respiratory Effort Sensor

INDICATIONS FOR USE:

The Gereonics Ultra-Piezo Respiratory Effort Sensor is intended for use in sleep disorders studies to measure respiratory effort for monitoring or recording on a physiological recording system.

The Ultra-Piezo Respiratory Effort Sensor is NOT intended for use as an Apnea Alarm.

Charles M. J. NDK.
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983449

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)