K991045

10.0 510(K) SUMMARY

10.1 Summary Information

10.1.1 Submitter's Name and Address

Jack E. McKenzie, Ph.D.
Mini-Mitter Co., Inc.
P.O. Box 3386
56885 Enterprise Dr.
Sunriver, Oregon 97707

Date summary was prepared: June 22, 1999

10.1.2 Name of Device

Trade Name: Mini-Logger® Series 2000

Common Name: Physiological Data Logging Device

Classification Name: Physiological signal conditioner (Product Code GYE)

10.1.3 Identification of predicate device

Vitalog HMS-5000

510(k) Number : K914085

10.1.4 Device Description

10.1.4.1 Functions of the device

The *Mini-Logger®* Series 2000 is a compact physiological data logger whose physical size and appearance are similar to a small TV remote control. The *Mini-Logger®* is powered from two replaceable, non-rechargeable lithium cells. The *Mini-Logger®* is generally worn in the shirt pocket or on a belt using its optional soft pouch. Direct-wired probes used to sense the physiological data are plugged into one or more of the four available data input channels.

10.1.4.2 Basic scientific concepts

The device acquires and logs digital data and resistances whose values represent the amplitudes of physiological signals. The physiological signals are temperature, heart rate, heart inter-beat-interval (IBI), counts representing gross motor activity, and resistance representing ambient light intensity. The scientific concepts and technologies that are used to sense the signals are summarized in Table 10.

TABLE 10. BASIC TECHNOLOGIES USED FOR PHYSIOLOGICAL SIGNAL RECORDING IN *MINI-LOGGER®* SENSOR PROBES.

Physiological Parameter	Sensor Used	Sensor Technology	Signal Obtained
Skin, ear canal, rectal temperature	Thermistor probe	Thermistor resistance varies uniquely with temperature.	Resistance.
Heart rate	Polar chest band	Low-impedance ECG skin electrode and high-impedance signal amplifier	Digital pulse for each heart beat.
Heart IBI	Polar chest band	Low-impedance ECG skin electrode and high-impedance signal amplifier	Digital pulse for each heart beat.
Gross motor activity	Motion-sensitive switch	Hermetically-sealed and encapsulated switch	Switch closures which provide digital pulses.
Ambient light	Photoconductive sensor	Photoconductor whose resistance varies with changing light levels.	Resistance.

10.1.4.3 Physical characteristics

Pertinent physical characteristics of the *Mini-Logger®* data logger are shown in Table 11.

TABLE 11. PHYSICAL CHARACTERISTICS OF *MINI-LOGGER®*.

Parameter	**Value**
Size	65x120x22 mm
Weight	125 grams
Battery type	3.6 volt lithium cells (2 each)
Moisture susceptibility	Not water resistant
Memory	128 Kilobyte or 1 Megabyte
Storage Temperature	-10 C to 50 C at 0-95% relative humidity
Operating Temperature	0 C to 40 C

10.1.5 Statement of the intended use of the device.

The *Mini-Logger®* is an ambulatory logging device that enables out-patient data collection for clinical and research applications. The *Mini-Logger®* is a compact, lightweight, physiological data logger for monitoring heart rate or inter-beat-interval (IBI), temperature, ambient light, and activity. The *Mini-Logger®* can be used in behavioral and circadian rhythm studies, sleep research, occupational health and sports medicine research, obesity/weight loss studies, behavioral and addiction studies. The device can be used for any assement of human heart rate or inter-beat-interval, temperature, and activity that requires logging of data over time and an integrated analysis of the forementioned parameters. The *Mini-Logger®* may be used in any instance where quantifiable analysis of physiological data is desirable.

10.1.6 How the technological characteristics of the device compare to those of the predicate device:

The *Mini-Logger®* and theVITALOG HMS-5000 Pocket Polygraph (FDA 510(k) Number: K914085) are both diagnostic test systems based upon the concept of a portable, unattended physiological monitor that logs sensor-input physiological data to the logging device. The device communicates the data with an IBM-compatible computer. These devices are both solid-state monitors with user-definable data collection algorithms, numbers of channels, types of channels, and with the ability to store data until it is down-loaded into the PC. The *Mini-Logger®* and theVITALOG HMS-5000 Pocket Polygraph are of similar size and weight. Both devices have an internal clock and event marker to time-stamp and mark data for later interpretation. . The *Mini-Logger®* has five specific types of data that can be input: temperature, gross motor activity, heart rate, heart inter-beat-interval (IBI) and ambient light. The VITALOG HMS-5000 Pocket Polygraph has the potential for twenty-three sensor inputs to include temperature, gross motor activity, heart rate, and ambient light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 1999

Jack E. McKenzie, Ph.D.
Vice President of Market Development
Mini Mitter Co., Inc.
P.O. Box 3386
Sunriver, Oregon 97707

Re: K991045
Trade Name: Mini-Logger® Series 2000
Regulatory Class: II
Product Code: GWK
Dated: June 22, 1999
Received: June 24, 1999

Dear Dr. McKenzie:

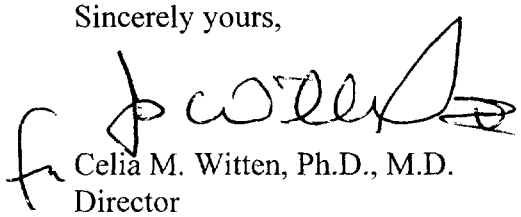
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 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.

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) 594-4595. 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

2.0 INDICATIONS FOR USE

510(k) Number (if known): K991045

Device Name: *Mini-Logger® Series 2000*

Indications for Use:

The *Mini-Logger® Series 2000* (hereafter referred to as *Mini-Logger*) is a compact, lightweight, physiological data logger for monitoring heart rate, inter-beat-interval (IBI), temperature, ambient light, and activity. The *Mini-Logger®* can be used in behavioral and circadian rhythm studies, sleep research, occupational health and sports medicine research, and obesity/weight loss studies. The device can be used for any assement of human heart rate or IBI, temperature, and activity that requires logging of data over time and an integrated analysis of the forementioned parameters. The *Mini-Logger®* may be used in any instance where quantifiable analysis of physiological data is desirable.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991045