JUL 23 1998

K973347

Spiracle Technology
TDx PRM Pulmonary Resuscitation Monitor
510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter
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Name of Device

Trade Name:	TDx PRM Pulmonary Resuscitation Monitor
Common Names:	Respiratory Monitor
Classification Name:	Airway Pressure Monitor
	21 C.F.R. 868.2600

Predicate Devices

(1) Bird Mean Airway Pressure Monitor (K812140)
(2) Sechrist Industries, Inc., Airway Pressure Monitor Model 400 (K814608)

Intended Use

The TDx PRM is intended to be used as an accessory to emergency resuscitators to monitor ventilatory functions including peak inspiratory pressure, respiratory rate, positive end expiratory pressure, and inspiratory/expiratory time ratio.

Technological Characteristics and Substantial Equivalence

The TDx PRM is intended to be used as an accessory to emergency resuscitators to monitor ventilatory functions. It is a small, portable battery operated device that attaches to bag mask resuscitators, oxygen powered demand valve resuscitators or automatic transport ventilators, which may not be equipped with pressure gauges for the purpose of patient airway monitoring. The TDx PRM monitors the following patient parameters: peak inspiratory pressure, breath frequency, inspiratory and expiratory times, positive end expiratory pressure ("PEEP"). The TDx PRM also offers a cardiopulmonary resuscitation metronome to

assist in the pacing of cardiopulmonary resuscitation efforts. The TDx PRM performs no diagnostic or therapeutic functions; it functions solely as a patient monitor and does not provide any patient alarms. Moreover, the TDx PRM has no direct patient contact; transmission of airborne pathogens is prevented by means of standard bacterial filters such as are routinely used with emergency resuscitation equipment.

The TDx PRM is substantially equivalent to other airway pressure monitors including the Bird Mean Airway Pressure Monitor (K812140) and Sechrist Industries, Inc., Airway Pressure Monitor Model 400 (K814608). These predicate devices, like the TDx PRM are microprocessor-controlled devices that utilize a electronic pressure transducer. Additionally, the predicate devices, like the TDx PRM, calculate and display breath rate, peak inspiratory pressure, inspiratory/expiratory time ratio, and positive end expiratory pressure.

Performance Data

Extensive functional testing of the TDx PRM has been performed. In addition, testing of the device has been performed under various environmental conditions, including impact/drop testing, storage temperature testing, electromagnetic interference testing, electrostatic discharge testing, spill resistance testing and surface temperature testing. Power supply testing also was performed; these tests included battery life testing and low power icon testing. The functional, environmental and power supply testing performed on the device demonstrated that it meets its performance objectives and complies with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1998

Mr. Guy Gansel
Spiracle Technology
16520 Harbor Boulevard, Suite "D"
Fountain Valley, CA 92708-1360

Re: K973347
TD_x PRM
Regulatory Class: II (two)
Product Code: 73 CAP
Dated: May 8, 1998
Received: May 11, 1998

Dear Mr. Gansel:

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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with

the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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

Spiracle Technology
TDx PRM Pulmonary Resuscitation Monitor
Indications for Use Statement

510(k) Reference Number:

This is an initial submission; no number has yet been assigned.

Statement of Indications for Use:

The TDx PRM is intended to be used as an accessory to emergency resuscitators and ventilators to monitor ventilatory functions including peak inspiratory pressure, respiratory rate, positive end expiratory pressure, and inspiratory/expiratory time ratio.

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K973347

℞ Prescription use