K992421

Comparison to Predicate Device

The modified design will differ from the predicate device in that it will only monitor low oxygen pressure, will be used with portable gas supply systems, and will include the pressure switch within the device.

Device Description and Intended Use

The Guardian™ Low Pressure Monitor Model 34076 will consist of the following major sub-components:

- *Circuit board with battery holder and battery*
- *Pressure switch*
- *Manifold and medical gas fittings (DISS)*
- *Protective cover*

The intended major functional characteristics of the device are:

- *Audibly indicate proper initialization upon insertion of the battery (i.e. power up)*
- *Audibly indicate low tank pressure*
- *Audibly indicate low remaining battery life, as determined by battery voltage*

Applicable Standards and Non-Clinical Testing

The system is designed and tested to meet the requirements of the American Dental Association (ADA) Acceptance Guidelines for Nitrous Oxide-Oxygen Conscious Sedation Systems.

Potential Adverse Health Effects

The modified design does not degrade the safety of the device. The Guardian™ Low Pressure Alarm model 34076 has been designed to either completely eliminate or mitigate all known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program. One or more of the following means (in order of preference) was used to implement mitigation of health hazards identified by the risk management program:

1. Design modifications.
2. Detection of hazard conditions and alerting of the user through alarms and visual indications.
3. Identification of any potentially undetectable health hazard conditions in the instruction manual and other device labeling.

The user must be qualified in dental analgesia procedures, trained in the use of the system, and must be familiar with all labeling and instructions for use associated with the equipment. The user of the device is advised to thoroughly understand the use of the equipment, and familiarize themselves with the location and function of all relevant controls and alarms prior to using the equipment.

Accutron, Inc. believes that the Guardian™ Low Pressure Alarm is safe and effective when used as instructed by knowledgeable and trained personnel, and performs as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1999

Ms. Dottie Knechtel
Accutron, Inc.
2020 W. Melinda Lane
Phoenix, AZ 85027

Re: K992421
Guardian™ Low Pressure Alarm Accessory
Regulatory Class: II (two)
Product Code: 73 ELI
Dated: September 27, 1999
Received: October 5, 1999

Dear Ms. Knechtel:

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,

Joanne A Weitzstauer for C

Wolf Sapirstein, M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K992421

Device Name: Guardian Low Pressure Alarm

Indications for Use:

Accessory device for use with nitrous oxide / oxygen sedation systems to monitor the medical gas system for a low oxygen pressure condition (less than 40 psi), and activate an audio alarm when this condition exists.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992421

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____