MAR 1 2 2004

510(k) Number: K033503

Date: MARCH 12 2004

510(k) Summary

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

Accutron, Inc.
1733 W. Parkside Lane
Phoenix, AZ 85027

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Ave., Golden, CO USA
Tel: 303-234-9412 / Fax: 303-234-9413

Date Prepared

March 11, 2004

Trade Name of Device

RFS Vacuum Gauge Scavenging Circuit

Common Name of Device

Scavenging Circuit

Classification Name

Apparatus, Gas-Scavenging

510(k) Classification

868.5430 Class II Product Code: CBN

Device Description

The RFS Vacuum Gauge Scavenging Circuit is designed for the removal of patient expired and excess gases during nitrous oxide / oxygen sedation procedures. For proper operation, the scavenging circuit must be connected to a vacuum pump capable of providing at least 45 LPM of vacuum flow, at an operating vacuum pressure of 8 in Hg. The vacuum pump should vent exhaust gases to the outside of the building, away from fresh air intakes, windows, or walkways.

The scavenging circuit consists of the scavenging hub, which connects to a nasal hood; exhaust tubing and connectors; and the RFS Vacuum Gauge. The nasal hood fits over the patient's nasal cavity, which serves to deliver medical gases to the patient and which allows removal of expired, excess, and unused medical gases from the nasal hood and surrounding areas.

This device measures pressure, not flow. Setting the float ball at the yellow indicator level determines correct vacuum-pressure. This will result in the NIOSH recommended 45 LPM vacuum-flow rate, provided the mask is correctly attached, and there are no kinks or obstructions in the flow path.

Model Variations

There are two model variations: Detachable Remote Mount and Chair Mount. While the physical arrangement of exhaust tubing and appearance varies, the operating principles are the same for both model variations.

Intended Use

To be used in nitrous oxide/oxygen sedation systems for the delivery to a patient a mixture of nitrous oxide and oxygen gases, for the removal from the treatment location of gases expired by the patient, and removal from the treatment location any excess gases delivered to a patient.

Predicate Devices

K965239 PIP Low Profile Scavenging System (Models 260, 260U)

Risk Management

This device has been designed to either completely eliminate or mitigate 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.

The user must be qualified in dental analgesic/nitrous oxide sedation procedures, and must be familiar with all labeling and instructions for use associated with the device. The company believes many device health hazards are due to user error, or failure to follow instructions for use.

Accutron believes that the RFS Vacuum Gauge Scavenging Circuit is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

Accutron, Incorporated
C/O Mr. Robert Clark
Medical Device Regulatory Advisors
13605 West 7th Avenue
Golden, Colorado 80401-4604

Re: K033503
Trade/Device Name: RFS Vacuum Gauge Scavenging Circuit
Regulation Number: 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: II
Product Code: CBN
Dated: February 11, 2004
Received: February 12, 2004

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033503

Device Name: RFS Vacuum Gauge Scavenging Circuit

Indications for Use:

To be used in nitrous oxide/oxygen sedation systems for the delivery to a patient a mixture of nitrous oxide and oxygen gases, for the removal from the treatment location of gases expired by the patient, and removal from the treatment location any excess gases delivered to a patient.

Prescription Use ___Y___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

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