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 West Parkside Lane
Phoenix, AZ, 85027 USA

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Ave.,
Golden, CO 80401 USA

Date Prepared

August 24, 2005

Trade Name of Device

Accutron Digital Ultra Analgesia Gas Machine

Classification Name

Gas-Machine, Anesthesia

510(k) Classification

21CFR§868.5160
Product Code: BSZ

Device Description

The Accutron Digital Ultra Analgesia Gas Machine precisely meters oxygen and nitrous oxide medical gases for conscious sedation of patients in dental offices and hospitals. With the device, the attending physician or dentist is able to set both the percentage of nitrous oxide and the total flow to a desired level of sedation and flow.

The Digital Ultra Analgesia Gas Machine has been designed with built in safety features that prevent the level of oxygen gas from falling below 30% of total flow, mechanical features that prevent the mix-up of gases, and fail-safe features to prevent the flow of nitrous oxide in the absence of oxygen gas.

Intended Use

The Digital Ultra Analgesia Gas Machine is intended for use in nitrous oxide-oxygen sedation systems for delivering to a patient a mixture of nitrous oxide and oxygen gases with a maximum nitrous oxide concentration of 70%.

Predicate Devices

K970163 Technical Medical Products Model 20 Alpha MX / Model 30 Ultra PC manufactured by Accutron Inc., Phoenix AZ.

K945722 Matrx MDM, RA manufactured by Matrx Medical, Inc., Orchard Park, New York.

Voluntary Standards

EN 60601-1 / IEC 60601-1, "Medical Electrical Equipment - Part 1: General Requirements for Safety"

EN 60601-1-2 / IEC 60601-1-2, "Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests"

ISO 5356-1, "Anesthetic and respiratory equipment – conical connectors"

ASTM F1054-01, "Standard specification for conical fittings"

CGA C-9:1988, "Standard color marking of compressed gas containers for medical use"

CGA V-5:2000, "Diameter-Index Safety System (non-interchangeable low pressure connections for medical gas applications)"

ADA Recommendations

The Accutron Digital Ultra Analgesia Gas Machine has been designed to meet the recommendations of the American Dental Association.

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 conscious sedation procedures, and must be familiar with all labeling and instructions for use associated with the device.

Accutron Inc. believes that the Digital Ultra Analgesia Gas Machine 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

NOV 2 3 2005

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

Re: K052335
Trade/Device Name: Accutron Digital Ultra Analgesia Gas Machine
Regulation Number: 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: November 14, 2005
Received: November 15, 2005

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 (240) 276-0120. 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K052335

Device Name: Accutron Digital Ultra Analgesia Gas Machine

Indications For Use:

To be used in nitrous oxide-oxygen sedation systems for delivering to a patient a mixture of nitrous oxide and oxygen gases with a maximum nitrous oxide concentration of 70%.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...on Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...(k) Number: K052335