OCT 24 2005

510(K) Summary

Medical Electronic Devices Corporation

Inogen Satellite Conserver SC-100

Submitter Information:

Medical Electronic Devices Corporation
2807 Oregon Court, D6
Torrance, California 90503

Submitter's Name: Thomas Wenzel
Phone: (310) 618-0306
FAX: (310)618-1034

Date Submitted: **9/9/05**

Device Name:

Proprietary Name: Inogen Satellite Conserver

Common Name: Oxygen Conserver

Classification Name: Non Continuous Ventilator (IPPB)

Predicate Device Equivalence:

Substantial equivalence is claimed to the Inogen Satellite Conserver SC-100 (K033197), CHAD Therapeutics Oxymatic Model 411 (K003455), and Invacare Venture IDD Oxygen Conserving Device (K002284).

Device Description:

The Inogen Satellite Conserver is a battery operated electronic device that is microprocessor controlled and contains a breath sensor and normally closed valve. The device is connected to an oxygen supply source and upon detecting the beginning of an inhalation; the device delivers a bolus of oxygen that is equivalent in most users, depending on the flow setting, to 1 to 5 liters per minute constant flow.

The Inogen Satellite Conserver can be used with bottled oxygen, liquid oxygen systems and as an accessory to the Inogen One Oxygen Concentrator (K032818). The device uses these systems as its oxygen supply and is connected by an oxygen supply tube.

Indications For Use:

The Inogen Satellite Conserver is intended for use to conserve oxygen for patients prescribed supplemental oxygen and use nasal cannulas as part of an oxygen delivery system including an oxygen concentrator, compressed oxygen cylinders, or liquid oxygen system.

Comparison of Technological Characteristics:

The Inogen Satellite Conserver has the same technological characteristics as the predicate device, i.e. Inogen Satellite Conserver (K033197). The electronic circuitry, control software, and device enclosure of the new device are identical to the Inogen Satellite Conserver (K033197). This 510(K) is a change in the Indications for Use only, adding compressed oxygen cylinders and liquid oxygen systems as additional sources of oxygen.

Summary of Testing:

Testing of the original Inogen Satellite Conserver contained extensive software validation testing, safety testing, mechanical testing, performance testing, and EMI/EMC testing. Since there was no change to the device's hardware or software these tests are applicable to the new device.

Comprehensive performance testing with compressed oxygen cylinders and liquid oxygen systems was done to ensure that the device functioned within its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2005

Mr. Thomas Wenzel
President
Medical Electronic Devices, Incorporated
2807 Oregon Court, Unit D6
Torrance, California 90503

Re: K052563
Trade/Device Name: Inogen Satellite Conserver
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: September 9, 2005
Received: September 19, 2005

Dear Mr. Wenzel:

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.

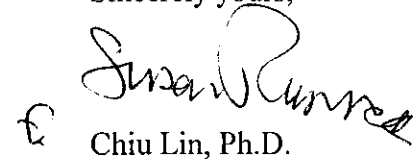
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Inogen Satellite Conserver

Indications For Use:

Intended for use to conserve oxygen for patients prescribed supplemental oxygen and use nasal cannulas as part of an oxygen delivery system including an oxygen concentrator, compressed oxygen cylinder, or liquid oxygen system.

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

510(k) Number K052563