APR 1 0 2006

K060193

510(k) SUMMARY

Oceanic Medical Products, Inc. Magellan-2200 Model-2 Anesthesia Machine

Oceanic Medical Products, Inc.
8005 Shannon Industrial Park Lane
Atchison, KS 66002

Telephone: 913 874 2000
Facsimile: 913 874 2005

William M. Gates, VP Innovation and Development

Date Prepared: March 24, 2006

Howard M. Holstein
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street N.W.
Washington, DC 20004-1109

Telephone: 202 637 5600
Facsimile: 202 637 5910

Trade Name:	**Magellan-2200 Model-2 Anesthesia Machine**
Common Name:	**Anesthesia Machine**
Classification Name:	**Gas Machine, Anesthesia**
C.F.R. Section:	**21 C.F.R. § 868.5160**
Product Code :	**BSZ**
Predicate Device:	**Magellan-2200 Model-1 Anesthesia Machine (K010613)**
Manufacturer:	**Oceanic Medical Products, Inc.**
Intended Use:	The Magellan-2200 Model-2 Anesthesia Machine is intended for spontaneous, manually assisted or automatic ventilation of patients during anesthesia. It may be used for the delivery of gases and anesthetic vapor. It is capable of monitor/alarm functions for oxygen concentration, breathing pressure and respiratory volumes.
Indicated Use:	The Magellan-2200 Model-2 Anesthesia Machine is intended for spontaneous, manually assisted or automatic ventilation of

patients during anesthesia. It may be used for the delivery of gases and anesthetic vapor. It is capable of monitor/alarm functions for oxygen concentration, breathing pressure and respiratory volumes.

Technological Characteristics:

The Magellan-2200 Model-2 consists of the following components:

Gas Manifold with Safety Connections
Low Pressure Oxygen Alarm
Oxygen and Air Pressure Gauges
Oxygen Auxiliary Flow Selector
Oxygen and Air Flowmeters
Oxygen Flush Button
Ventilator Gas Power Selector Toggle Switch
Anesthetic Vaporizer
Common Gas Outlet
Bag-Vent Switch with Pressure Relief Valve
Mechanical Ventilator with Pressure Relief Valve
Air Compressor with Battery and Electrical Charger
Ventilator and Power Source Alarms
Bellows with Pressure Relief Valve
Carbon Dioxide Absorber with one way valves
Waste-gas Scavenger
Oxygen Analyzer/Monitor

Performance Data:

The Magellan-2200 Model-2 Anesthesia Machine was tested according to the same protocols used for its predicate, the Magellan-2200 Model-1 in order to ascertain if the system worked as designed with the replacement ventilator and its electrically-powered air compressor source. All recommended mechanical and electrical testing was completed simultaneously by the manufacturers of the anesthesia machine and/or the ventilator.

In all instances, the Magellan-2200 Model-2 functioned as intended and the bench testing and electrical testing results observed were as expected.

Substantial Equivalence:

The Magellan-2200 Model-2 Anesthesia Machine is as safe and effective as the Magellan-2200 Model-1 Anesthesia Machine. The Magellan-2200 Model-2 Anesthesia Machine as the same intended uses and same indications, technological characteristics and principles of operation as its predicate device. The minor technological difference between the Magellan-2200 Model-2 Anesthesia Machine and it predicate device raise no new issues of safety or effectiveness. Thus, the Magellan-2200 Model-2 Anesthesia Machine is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2006

Oceanic Medical Products, Incorporated
C/O Mr. Howard M. Holstein
Hogan & Hartson, Limited Liability Partnership
555 Thirteenth Street, NW
Washington DC 20004

Re: K060193
Trade/Device Name: Magellan-2200 Model-2 Anesthesia Machine
Regulation Number: 868.5160
Regulation Name: Gas machine for anesthesia or analgesia
Regulatory Class: II
Product Code: BSZ
Dated: January 25, 2006
Received: January 25, 2006

Dear Mr. Holstein:

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 (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 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 continue 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) 276-0115. 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

Indications for Use

510(k) Number (if known):_________

Device Name: Magellan-2200 Model-2 Anesthesia Machine

Indications for Use:

The Magellan-2200 Model-2 Anesthesia Machine is **Intended** for spontaneous, manually assisted or automatic ventilation of patients during anesthesia. It may be used for the delivery of gases and anesthetic vapor. It is capable of monitor/alarm functions for oxygen concentration, breathing pressure and respiratory volumes.

The Magellan-2200 Model-2 Anesthesia Machine in **Indicated** for use with spontaneous, manually assisted or automatic ventilation of patients during anesthesia. It may be used for the delivery of gases and anesthetic vapor. It is capable of monitor/alarm functions for oxygen concentration, breathing pressure and respiratory volumes.

Prescription Use__X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (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)

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