510(k) SUMMARY K072420

Oceanic Medical Products, Inc.'s Magellan-2200, Model-3 Anesthesia Machine

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

William M. Gates
Vice President, Innovation and Development
Oceanic Medical Products, Inc.
8005 Shannon Industrial Park Lane
Atchison, Kansas 66002
Telephone: (913) 874-2000
Facsimile: (913) 874-2005

JAN 22 2008

OR

Howard M. Holstein, Esq.
Hogan and Hartson, LLP
555 Thirteenth Street, NW
Washington, DC, 20004
Telephone: (202) 637-5813
Facsimile: (202) 637-5910

Date Prepared: December 26, 2007

Name of Device and Name/Address of Sponsor

Magellan-2200, Model-3 Anesthesia Machine

Oceanic Medical Products, Inc.
8005 Shannon Industrial Park Lane
Atchison, Kansas 66002
Telephone: (913) 874-2000
Facsimile: (913) 874-2005

Common or Usual Name

Anesthesia Gas Machine

Classification Name

Gas Machine, Anesthesia

Product Code

BSZ

Regulation Number

21 C.F.R. § 868.5160

Predicate Devices

Oceanic Medical Products, Inc.'s Magellan-2200, Model-1 Anesthesia Machine (K010613)
Cardinal Medical Specialties OBA-1 Anesthesia Machine (K000859)

Purpose of the Special 510(k) Notice

The Magellan-2200, Model-3 Anesthesia Machine is a modification to the Magellan-2200, Model-1 Anesthesia Machine.

Intended Use

The Magellan-2200, Model-3 Anesthesia Machine is intended for spontaneous or manually assisted 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 source oxygen pressure.

Technological Characteristics

The Model-3 is a gas machine for anesthesia or analgesia. The device consists of the following components: an inlet gas manifold for oxygen and air; pressure gauges for oxygen and air; a low-pressure alarm for inlet oxygen surveillance; an oxygen analyzer and monitor; an oxygen flow selector for nasal cannula or oxygen mask for pre- and post-anesthesia use; an oxygen flush button; oxygen and air flowmeters; an agent-specific vaporizer; a common gas outlet; a carbon dioxide absorber with one way valves; and a reservoir bag/pressure gauge/pressure relief/scavenger outlet arm.

Substantial Equivalence

The Model-3 has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate devices. Thus, the Model-3 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2008

Oceanic Medical Products, Incorporated
C/O Mr. Howard M. Holstein
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

Re: K072420
Trade/Device Name: Magellan-2200, Model-3 Anesthesia Machine
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: December 26, 2007
Received: December 26, 2007

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 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.

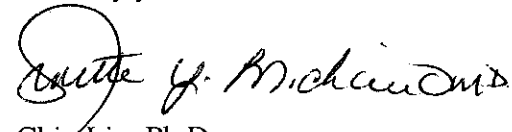
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Chin 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

Attachment 8

Indications for Use Statement

Device Name: Magellan-2200, Model-3 Anesthesia Machine

Indications for Use:

The Magellan-2200, Model-3 Anesthesia Machine is intended/indicated for spontaneous or manually assisted 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 source oxygen pressure.

Prescription Use __X__ (Per 21 C.F.R. 801.109)	AND/OR	Over-The-Counter Use ___ (Per 21 C.F.R. 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: K072420