K081335

Section 5 - 510(k) Summary or 510(k) Statement

510(k) Summary

NOV 14 2008

Submitter Information
Tenacore Holdings, Inc
647 E. Young Street
Santa Ana, CA 92705

Contact
Brand Caso, QA Director Ph: 714-444-4643 Fx: 714-549-7835

Date Prepared
May 1, 2008

Product Name
Tenacore Oxygen Blender

Predicate Device
K925982

Product Description
The Tenacore Oxygen Blender is typically a wall-mounted unit that provides inlets for medical grade air and therapeutic oxygen. The percentage of oxygen to air can be adjusted from 21-100%.

Intended Use
The Tenacore Oxygen Blender, is intended for non-invasive mixing and delivery of a ratio of therapeutic oxygen and medical grade air as a stand-alone unit or as a component of a respiratory support apparatus.

Comparison to Predicate Device

	Tenacore Model	Bird Air/Oxygen Microblender
Intended use	The Tenacore Oxygen Blender, is intended for non-invasive mixing and delivery of a ratio of therapeutic oxygen and medical grade air as a stand-alone unit or as a component of a respiratory support apparatus.	Similar
Primary Material	Aluminum	same
Design Shape	Block	same
Patient use/reuse	Reuse	same
Sterility	Non-sterile	same
Description of patient attachment	Unit does not directly attached to patient	same
Connector design	Various	same

Internal Components	Same design, form, function and material as predicate	same
Dimensions	same	same
Accuracy	+/- 3%	same

Performance Data & Conclusions

Performance testing was conducted as required by standards: EN ISO 15001:2004; 60601-1; 9703-3:1998; 601-1:1988 and IEC 79-4:1975

Electrical safety testing was not performed, as there are no electrical components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Brand Caso
Director
Tenacore Holdings, Incorporated
647 East Young Street
Santa Ana, California 92705

NOV 1 4 2008

Re: K081335
Trade/Device Name: Tenacore Oxygen Blender
Regulation Number: 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: October 29, 2008
Received: November 4, 2008

Dear Mr. Caso:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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: Tenacore Oxygen Blender

Indications for Use:

The Tenacore Oxygen Blender, is intended for non-invasive mixing and delivery of a ratio of therapeutic oxygen and medical grade air as a stand-alone unit or as a component of a respiratory support apparatus.

Prescription Use ___XX____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

V. Maly for MSC

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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