AMRON INTERNATIONAL

JUN 1 9 2002

510(k) Summary for Amron International Treatment Hood (K011592)

Date
March 27, 2002

To
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Submitter
Amron International Diving Supply, Inc.
759 West Fourth Avenue
Escondido, CA 92025
Phone: (760) 746-3834
Fax: (760) 746-1508
Contact: Scott Ritchie

Name of Device
Proprietary Name: Amron Treatment Hood
Common/Usual Name: Treatment Hood

Equivalent Device
Sea-Long Medical Treatment Hood, 510(k) No. K010659

Device Description
The Amron International Oxygen Treatment Hood, Model 8891, was designed for easy use and cost effective operation within a multiplace or monoplace hyperbaric chamber. The hood assembly is placed over a person's head for treating a person with a gas such as oxygen.

The assembly includes a reusable neck ring which fits over a user's head, a tubular latex neck seal with one end connected to the neck ring and the other configured to fit around the user's neck, and a transparent hood fastened to a hood ring that can be sealed against the neck ring.

Supply and exhaust tubes direct gas into and out the hood through ports located on the neck ring. The supply and exhaust locations allow oxygen to circulate easily throughout the hood increasing performance while reducing noise levels. Supply gas also helps cool the user reducing potential overheating and continuously defogs the hood's optical window.

AMRON INTERNATIONAL

510(k) Summary for Amron International Treatment Hood (K011592)

Intended Use

The Amron International Treatment Hood is intended to provide a means to administer gas/oxygen/air to a patient by a clinician in clinical multiplace or monoplace chamber system.

Technological Characteristics of Amron Hood Compared to Predicate Device

Non-clinical tests were run for performance at different flow rates and ATA. Oxygen and carbon dioxide levels, flow characteristics, sealing, fogging, cooling effect on patient, and noise level were also evaluated.

The Amron International Treatment Hood was found to be functionally identical to the Sea-Long Treatment Hood and their technological characteristics are the same.

Technological Characteristics	Amron Treatment Hood (K011592)	Sea-Long Treatment Hood (K010659)
Physical Size & Shape of Treatment Hood	12"Ø x 12" High cylinder shape	Same
Vinyl Hood with Ring	Clear vinyl hood attached to hood ring with viewing window	Same
Neck Ring	Offset neck ring with o-ring	Same
Supply & Exhaust Connectors	Molded in 22 mm connectors located on front of neck ring	Same
Multi-Access Port	Molded in and located on front of neck ring between supply & exhaust connectors	Same
Neck Seal	Attached to neck ring and seals around patient's neck	Same
Intended Use	For use in hyperbaric Oxygen Therapy (HOT)	Same

759 West Fourth Avenue • Escondido, CA 92025 USA
Phone: (760) 746-3834 • Fax: (760) 746-1508
E-mail: sales@amronintl.com • Web Site: www.amronintl.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2002

Amron International Diving Supply, Inc.
c/o Ms. Norma F. Ockwig
759 West Fourth Avenue
Escondido, CA 92025

Re: K011592
Amron Oxygen Treatment Hood
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II (two)
Product Code: CBF
Dated: undated
Received: March 29, 2002

Dear Ms. Ockwig:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011592

Device Name: Amron International Treatment Hood

Indications for Use:

The Amron International Treatment Hood is intended to provide a means to administer gas/oxygen/air to a patient by a clinician in clinical multiplace or monoplace chamber systems.

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011592