K072757

510(k) Summary

Owner Information
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Mound, MN 55364
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APR 22 2008

Contact Information
Bruce McKeeman

Preparation Date: August 25, 2007

- Trade name – Hyperbaric Dives Hyperbaric Chamber
- Common name – Portable Mild Hyperbaric Chamber
- **Classification name – Hyperbaric Chamber (868.5470, Product Code CBF)**

This submission is using the Gamow Bag/HTI Model-2, manufactured by HTI as the substantially equivalent devices. The FDA 510K numbers are K874752A for the Gamow bag and K001409 for the HTI Model-2. Also, the BLKS-307 Monoplace Hyperbaric Oxygen Treatment System is used as a substantial equivalent device with the FDA 510 number K060739.

Device Description

Hyperbaric Dive chambers are mild hyperbaric chambers for pressures less than 5 PSI. This chamber is designed after the Gamow bag. It is composed of an airtight bag which is zipped shut with a person inside. The bag is inflated with atmospheric air with a small electric pump. The Hyperbaric Dive chambers are inflated with the Gast DDL 30, DDL40, or DDL120. The Shallow Dive, The Dive, and the Grand Dive utilize a single airtight bag with a single zipper. The bags have two relief valves set to 3.9 and 4 PSI to ensure safe operation (The Shallow Dives are set to 2.9 and 3 PSI to achieve the lower pressure). The chambers all utilize two redundant fill valves (for pressurizing the chamber from the Gast pump), one - two access ports for sampling inside or outside air and one external pressure gauge. An optional pressure gauge can be added to the air sampling valve and positioned for viewing from the inside of the chamber. The Shallow Dive and the Dive weigh 15 pounds while the Grand Dive weighs 32 pounds. The compressor weighs 24 pounds. The bags are constructed of urethane coated nylon. The valves and ports are constructed of metal and plastic. The Shallow Dive is 7 feet long and 27 inches wide and attains 1.2 ATA (3 PSI), the Dive is 7 feet long and 27 inches wide and the Grand Dive is 9 feet long and 40 inches wide. These two chambers attain 1.3 ATA (4 PSI). All dimensions are with the devices inflated.

Indicated Use: Indications for Use: The Dive Series Hyperbaric Chambers are rugged and portable, intended to be used to treat:

Acute Altitude Sickness

As prescribed by or under the direction of a physician.

The device is intended for use in the home, physicians' offices, outdoors, hospitals/clinics.

Attribute	Gamow K874752A	HTI Model-2 K001409	The Shallow Dive Model HD220 510K K072757	The Dive Model HD250 510K K072757	The Grand Dive Model HD400 510K K072757
Intended Use	Acute Mountain Sickness (AMS) and its associated mild symptoms	Acute Mountain Sickness (AMS) and its associated mild symptoms	Same	Same	Same
Prescription Use	Yes	Yes	Yes	Yes	Yes
Intended population	People with High altitude mountain sickness	People with High altitude mountain sickness	Same	Same	Same
Intended place of use	home, physicians offices, outdoors, hospitals/clinics	home, physicians offices, outdoors, hospitals/clinics	Same	Same	Same
Weight	6.5 lbs.	11 lbs.	15 lbs.	15 lbs.	32 lbs.
Size Length X Width (inflated)	7' X 21"	7' X 21"	7' X 27"	7' X 27"	9' X 40"
Windows	2	3	2-3	2-3	2-4
Straps for transport	2	none	4	4	4
Relief Valves	Yes, plastic	Yes(plastic/ metal)	Yes	Yes	Yes
Dump Valve	Yes	Yes (two-way)	Yes Integrated in Relief an Fill valves	Yes Integrated in Relief an Fill valves	Yes Integrated in Relief an Fill valves
Operating Pressure	2-4 PSI/1-1.3 ATA	2-4 PSI/1-1.3 ATA	3 PSI/1-1.2 ATA	4 PSI/1-1.3 ATA	4 PSI/1-1.3 ATA
Method for inflation	Foot pump/compressor	Compressor	Compressor	Compressor	Compressor
Zipper	Pressure seal	Double zipper with seal flap two-way	Single airtight zipper	Single airtight zipper	Single airtight zipper
Chamber	420 denier & 33-39 oz. urethane coated nylon	420 denier & 33-39 oz. urethane coated nylon	Same HTI Model-2 K001409 NA for K060739	Same HTI Model-2 K001409 NA for K060739	Same HTI Model-2 K001409 NA for K060739
Relief Valves	Plastic	Stainless steel	Plastic and Metal	Plastic and Metal	Plastic and Metal
Compressor		Gast oil-less	Gast oil-less	Gast oil-less	Gast oil-less
Air Filtration on Compressor	Yes	Yes	Yes	Yes	Yes
Pressure Gauge	Yes	Yes	Yes	Yes	Yes
Operating Temperature	-50F to +125F	-50F to +125F	-50F to 125F	-50F to 125F	-50F to 125F
Contradictions	Patients with: colds, or flu symptoms - Recent Alcohol consumption - Blocked Ear Canals - Blocked Sinuses - Otic	Patients with: colds, or flu symptoms - Recent Alcohol consumption - Blocked Ear Canals - Blocked Sinuses - Otic	Patients with: colds, or flu symptoms - Recent Alcohol consumption - Blocked Ear Canals - Blocked Sinuses - Otic barotraumas	Patients with: colds, or flu symptoms - Recent Alcohol consumption - Blocked Ear Canals - Blocked Sinuses - Otic barotraumas - Excessive CO2 exposure	Patients with: colds, or flu symptoms - Recent Alcohol consumption - Blocked Ear Canals - Blocked Sinuses - Otic barotraumas - Excessive CO2 exposure

	barotraumas - Excessive CO2 exposure - Pulmonary hyper expansion Decompression Sickness	barotraumas - Excessive CO2 exposure - Pulmonary hyper expansion Decompression Sickness	- Excessive CO2 exposure - Pulmonary hyper expansion Decompression Sickness	- Pulmonary hyper expansion Decompression Sickness	- Pulmonary hyper expansion Decompression Sickness
Labeling	Compatible	Compatible	Compatible	Compatible	Compatible

Differences between other Legally Marketed Devices:

There is no significance difference between The Shallow Dive, The Dive, The Grand Dive and the predicate Gamow Bag K874752A and HTI Model-2 K001409.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

Mr. Bruce McKeeman
Manager
Summit to Sea
1744 Avocet Lane
Mound, Minnesota 55364

Re: K072757
Trade/Device Name: The Shallow Dive, The Dive, and The Grand Dive
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: January 28, 2008
Received: January 28, 2008

Dear Mr. McKeeman:

This letter corrects our substantially equivalent letter of February 8, 2008.

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) 276-0120. 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 (240) 276-3150 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

Enclosures

Indications for Use

510(k) Number (if known): K072757.

Device Name: The Shallow Dive, The Dive, and The Grand Dive

Indications for Use: The Dive Series Hyperbaric Chambers are rugged and portable, intended to be used to treat:

Acute Mountain sickness (AMS)

as prescribed by or under the direction of a physician.

Caution: Federal Law restricts this device to sale by or on the order of a physician.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number K072757