K051759

NOV 17 2005

Performance Hyperbarics

2599 A Olinda Rd

Makawao, HI 96768

Non-Confidential Summary of Safety and Effectiveness, 510(k) Submission

June 15, 2005

Performance Hyperbarics
2599 A Olinda Rd
Makawao, HI 96768

Tel - 808-573-8166
Fax- 808-573-8976
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Official Contact:	Spencer Feldman
Proprietary or Trade Name:	Flexi-Lite Hyperbaric Chamber
Common Used Name:	Mild Hyperbaric Chamber
Classification Name:	Hyperbaric Chamber
Regulatory Class:	Class II (two)
Product Code:	73 CBF
Device:	Flexible Hyperbaric Chamber with Air Compressor
Predicate Devices:	HTI - Gamow Bag -K874752A HTI - Mild Hyperbaric Chamber -K001409

Device Description

The Flexi-Lite flexible hyperbaric chamber is a mild hyperbaric chamber for pressures less than 5 psi. This lightweight and portable chamber utilizes atmospheric Air as supplied by a GAST model 0523 "oiless, breathable air compressor" to pressurize the chamber and provide a suitable environment for the occupant. The Flexi-Lite construction utilizes a dual bag design with the inner bag containing the pressure and an exterior bag to provide structural support. All components are attached to the inner bag utilizing bulkhead connections. It is outfitted with two externally mounted metal relief valves (set at 4 psi), two metal Air addition valves (one external & one internal), two metal depressurization valves (one external & one internal), two pressure gauges (one external & one internal), and one metal Air sampling port. In total it weighs 39 lbs (compressor adds another 54 lbs).

Intended Use

Indicated Use:	To provide mild hyperbaria for the treatment of Acute Mountain Sickness (AMS) and its associated mild symptoms
Environment of Use:	Home, Physicians office, Outdoor environments, Hospital, Sub-acute Institutions, Emergency Services.
Prescriptive Use:	Caution, Federal law restricts this device to sale by or on the order of a physcian.

Comparison To Predicate Devices

Attribute	Gamow K874752A	HTI Model-2 K001409	HTI Model-3 K001409	Flexi-Lite K051759
Intended Use	Acute Mountain Sickness (AMS) & associated symptoms	Acute Mountain Sickness (AMS) & associated symptoms	Acute Mountain Sickness (AMS) & associated symptoms	Acute Mountain Sickness (AMS) & associated symptoms
Prescription Use	Yes	Yes	Yes	Yes
Intended Population	Persons with high altitude mountain sickness	Persons with high altitude mountain sickness	Persons with high altitude mountain sickness	Persons with high altitude mountain sickness
Intended Environment of Use	Home, Physician Office, Outdoor, Hospital, Sub-acute facility, EMS	Home, Physician Office, Outdoor, Hospital, Sub-acute facility, EMS	Home, Physician Office, Outdoor, Hospital, Sub-acute facility, EMS	Home, Physician Office, Outdoor, Hospital, Sub-acute facility, EMS
Weight (lbs)	6.5	11	17	39
Size Length x inflated dia.	7 ft x 21 in	7 ft x 21 in	7 ft x 21 in	8 ft x 30 in
Windows	2	3	3	4
Straps for Transport	2	none	none	none
Relief Valves	Yes-Plastic	Yes-Metal	Yes-Metal	Yes, Qty-2-Metal
Dump Valve	yes	yes, 2-way	yes, 2-way	yes-Separate
Operating Pressure (psi)	2-4	2-4	2-4	2-4
Methods of Inflation	Foot pump / Compressor	Compressor	Compressor	GAST Model 0523 Compressor

Zipper	Pressure seal	Double zipper w/ seal-flap, 2-way	Double zipper w/ seal-flap, 2-way	Single zipper
Materials				
Attribute	**Gamow K874752A**	**HTI Model-2 K001409**	**HTI Model-3 K001409**	**Flexi-Lite K051759**
Chamber	420 denier-urethane coated nylon	420 denier and 33-39 oz urethane coated nylon	33-39 oz urethane coated nylon	inner bag-880 denier-urethane coated nylon outer bag- 2 x 2 basket weave, 2-side-urethane coated nylon
Relief valves	Plastic	Stainless Steel	Stainless Steel	Brass & Stainless
Compressor	GAST oil-less	GAST oil-less	GAST oil-less	GAST 0523 oil-less
Air Filtration on compressor	yes	yes	yes	yes
Pressure Gauge	yes	yes	yes	yes
Air Filtration on chamber	?	?	?	Yes

Ability for person inside to extricate themselves if needed	no	yes	yes	yes
Attribute	**Gamow K874752A**	**HTI Model-2 K001409**	**HTI Model-3 K001409**	**Flexi-Lite K051759**
Operating Temperatures	-50F to + 120F	-50F to + 120F	-50F to + 120F	-50F to + 120F
Contraindications	Patients with: -Colds or flu symptoms -Recent alcohol consumption -Blocked ear canals for any reason -Otic barotrauma -Excessive CO2 exposure -Pulmonary hyperexpansion -Decompression Sickness	Patients with: -Colds or flu symptoms -Recent alcohol consumption -Blocked ear canals for any reason -Otic barotrauma -Excessive CO2 exposure -Pulmonary hyperexpansion -Decompression Sickness	Patients with: -Colds or flu symptoms -Recent alcohol consumption -Blocked ear canals for any reason -Otic barotrauma -Excessive CO2 exposure -Pulmonary hyperexpansion -Decompression Sickness	Patients with: -Colds or flu symptoms -Recent alcohol consumption -Blocked ear canals for any reason -Otic barotrauma -Excessive CO2 exposure -Pulmonary hyperexpansion -Decompression Sickness
Labeling	Comparable	Comparable	Comparable	Comparable

Differences Between Other Legally Marketed Devices:

There are no significant differences between the FlexiLite and the predicates - Gamow Bag K874752A -HTI Models 2 or 3 K001409

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2005

Mr. Spencer Feldman
President
Performance Hyperbarics
2599 A Olinda Road
Makawao, Hawaii 96768

Re: K051759
Trade/Device Name: Flexi-Lite
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: October 21, 2005
Received: October 21, 2005

Dear Mr. Feldman:

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.

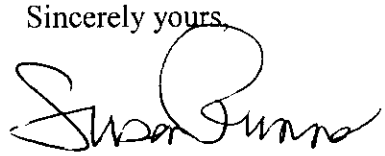
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

510(k) Submission
June 15, 2005

Indications For Use

510(k) Number (if known): K051759

Device Name: Flexi-Lite

Indications For Use: The Flexi-Lite Hyperbaric chamber is a rugged & portable hyperbaric chamber intended to be used in treating mild symptoms consistent with 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 ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...(k) Number: K051759