AUG 2 2000

K001409

Hyperbaric Technologies, Inc.
1 Sam Stratton Rd.
P.O. Box 69
Amsterdam, NY 12010

Non-Confidential Summary of Safety and Effectiveness

1-Aug-00

Hyperbaric Technologies, Inc.
1 Sam Stratton Rd.
PO Box 69
Amsterdam, NY 12010

Tel - (800) 382-2491

Fax - (518) 842-1031

Official Contact:	Peter A. Lewis - President
Proprietary or Trade Name:	Mild Hyperbaric Chambers
Common/Usual Name:	Mild Hyperbaria chamber
Classification Name:	Hyperbaric chamber
Device:	Mild Hyperbaric Chambers
Predicate Devices:	HTI - Gamow Bag - K874752A

Device Description:

The Hyperbaric Technologies product line, are mild Hyperbaria chambers for pressures less than 10 psi. These are lightweight and portable and utilize atmospheric air mixture for the person inside the chamber. There are various models which have the following characteristics and configurations - **Gamow Bag** ~ 7 lbs. - Lightweight unit, easier to transport; **Model 2** ~ 11 lbs. - Unit similar to Gamow but with metal fittings; **Model 3** ~ 17 lbs. - Unit with heavier gauge material and metal fittings; and **Model 4** ~ 250 lbs. - larger version.

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, Physician office, Outdoor environments, Hospital, Sub-acute Institutions, Emergency services

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Comparison to Predicate Devices:

Attribute	Gamow K874752A	Gamow current	Model 2	Model 3	Model 4
Intended use	Acute Mountain Sickness and associated symptoms	Acute Mountain Sickness and associated milde symptoms of AMS	Same	Same	Same
Prescription Use	Yes	Yes	Yes	Yes	Yes
Intended population	Persons with high altitude sickness	Same	same	same	same
Intended Environment of Use	Outdoor, home	Home, Physician Office, Outdoor, Hospital, sub-acute, Emergency services	same	same	same
Design Features					
Weight (lbs.)	6.5	6.5	11	17	250
Size - L x inflated dia.	7 ft x 21 "	7 ft x 21 "	7 ft x 21 "	7 ft x 21 "	Height 9 ft. By 54"
Windows	2	2	3	3	12
Straps for transport	Yes	Yes	None	None	None
Relief valves	Yes - Plastic	Yes - Plastic	Yes - metal	Yes - metal	Yes - metal
2 way dump valve	No	No	Yes	Yes	Yes
Operating pressures (psi)	2-4	2-4	2-4	2-4	2-4
Methods of inflation	Foot pump / Compressor	Foot pump / compressor	Compressor	Compressor	Compressor
Zipper	Pressure seal	Pressure seal	Double zipper with seal flap, 2 way	Double zipper with seal flap, 2 way	Double zipper with seal flap, 2 way
Materials					
Chamber	420 denier - urethane coated nylon	420 denier - urethane coated nylon	420 denier and 33-39 oz- urethane coated nylon	33- 39 oz urethane coated nylon	33- 39 oz urethane coated nylon
Relief valves	Plastic	Plastic	Stainless Steel	Stainless Steel	Stainless Steel

Attribute	Gamow K874752A	Gamow current	Model 2	Model 3	Model 4
Compressor - Gast oil-less	Yes	Yes	Yes	Yes	Yes
Air filtration on compressor	Yes	Yes	Yes	Yes	Yes
Pressure gauge	Yes	Yes	Yes	Yes	Yes
Ability for person inside to extricate themselves if needed	No	No	Yes	Yes	Yes
Operating temperatures	-50°F to +120°F	-50°F to +120°F	-50°F to +120°F	-50°F to +120°F	-50°F to +120°F
Contraindications	Patients with head colds or flu symptoms, having consumed alcohol recently, if ear canals are blocked for any reasons, otic barotrauma, decompression sickness, pulmonary hyperexpansion, excessive carbon dioxide exposure	Same	Same	Same	Same
Labeling	Comparable	Comparable	Comparable	Comparable	Comparable

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended devices and the predicate - Gamow Bag - K874752A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2000

Hyperbaric Technologies, Inc.
c/o Mr. Paul Dryden
ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055-9501

Re: K001409
Mild Hyperbaric Chamber
Regulatory Class: II (Two)
Product Code: 73 CBF
Dated: May 2, 2000
Received: May 4, 2000

Dear Mr. Dryden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K001409 (To be assigned)

Device Name: Mild hyperbaric chambers

Intended Use: To provide mild hyperbaria for the treatment of Acute Mountain Sickness (AMS) and its associated mild symptoms

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K 001409

Prescription Use ✓ (Per CFR 801.109) **or** **Over-the-counter use** __