Exhibit 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K101262

1. **Submitter's Identification:**

JUN 10 2010

Pressure Tech, Inc.
102 Woodcleft Avenue
Freeport, NY 11520

Phone: 516 546 2030
Contact: Charlie Johnson

Date Summary Prepared: February 16, 2010

2. **Name of the Device:**
Flexi-Lite

3. **Common or Usual Name:**
Hyperbaric Chamber
Regulation: 21 CFR868.5470
Product Code: CBF

4. **Predicate Device Information:**
K051759 Flexi-Lite Hyperbaric Chamber

5. **Device Description:**

The Flexi-Lite flexible hyperbaric chamber is a mild hyperbaric chamber for pressures less than 4 psi. This lightweight and portable chamber utilizes atmospheric Air as supplied by a GAST model 0523/1023 "oil-less, 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).

6. **Intended Use:**

The Flexi-Lite Hyperbaric chamber is a 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.

7. **Comparison to Predicate Devices:**

Item	Subject Device	Substantially Equivalent (SE) or different
Intended 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.	SE
Intended population	Persons with High altitude mountain sickness	SE
Intended Environment of use	Home, Physician office, outdoor, hospital, subacute facility, EMS	SE
Relief valves	Yes – Qty 2 metal	SE
Dump valve	Yes – separate	SE
Operating Pressure (psi)	2-4	SE
Method of inflation	GAST Model 0523/1023 Compressor	SE
Chamber	Inner bag – 880 denier-urethand coated nylon Outer bag 2 x 2 basket wearve, 2-side –urethane coated nylone	SE
Relief valves	Brass and stainless	SE
Compressor	GAST 0523/1023 oil-less	SE
Air Filtration on compressor	Yes	SE
Pressure Gauge	Yes	SE
Air filtration on chamber	Yes	SE

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Bench testing was performed as determined by the hazard analysis. The Flexi-Lite passed all bench testing.

10. Conclusions:

There are no significant differences between the Flexi-Lite and the predicate device therefore we have concluded that the Flexi-Lite is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pressure-Tech, Incorporated
C/O Ms. Maria Griffin
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

JUN 10 2010

Re: K101262
Trade/Device Name: Flexi-Lite
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: May 27, 2010
Received: May 28, 2010

Dear Ms. Griffin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K101262

Device Name: Flexi-Lite

Indications For Use:

The Flexi-Lite Hyperbaric chamber is a 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 ___X__ **(Per 21 CFR 801 Subpart D)** 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)

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

510(k) Number: K101262