Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

8/11/2007
Submission ID: DW-2007-0609

Hyperbaric Health Pty Ltd
119-123 Woodlands Drive
BRAESIDE VIC 3195

Attention: Glen Hawkins

NOTIFICATION OF INCLUSION OF A MEDICAL DEVICE
Application for inclusion in the ARTG: DV-20071022-DA-048904-11
Your Reference: Perry Baromedical Sigma 34/40
ARTG No: 147088

Attached please find the certificate(s) provided as a result of your recent application(s) for inclusion of a Medical Device on the Australian Register of Therapeutic Goods (ARTG).

These goods are included subject to the conditions as stated in the Certificate(s) for Inclusion of a Medical Device related to this notification.

The TGA Financial Services Group will issue an invoice for annual fees. The inclusion of the goods will commence on the day specified for the purpose in the Certificate for Inclusion of a Medical Device. The goods **may not be supplied prior to this date. Continued inclusion will** be subject to payment of the annual fees.

All future communications regarding the approval should include the ARTG Number as a reference. The contact number for any questions is 1800 141 144.

Delegate of the Secretary
Application Entry and Coordination Section
Office of Device, Blood and Tissues

ENC: Certificate for Inclusion of a Medical Device

TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100, Woden, ACT 2606, Australia
Telephone: (02)6232 8444. Fax (02)6232 8241
ABN 40 939 406 804

Commonwealth Department of Health and Ageing

CERTIFICATE FOR INCLUSION OF A MEDICAL DEVICE

ARTG Number 147088

ARTG Labelname Hyperbaric Health Pty Ltd - Chamber, patient, hyperbaric

Sponsor Hyperbaric Health Pty Ltd

Commencement Date 07/11/2007

Manufacturer Perry Baromedical Corporation United States Of America

Device Class Class IIb
GMDN Code 12061 Chamber, patient, hyperbaric

ARTG Product Number and Name
235321 Chamber, patient, hyperbaric

The above Medical Device is Included in the Australian Register of Therapeutic Goods subject to the following conditions

Standard Conditons
The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

Each sponsor shall retain records of the distribution of all of the sponsor's medical

devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

The sponsor shall provide to the Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, three consecutive reports which include information of a kind specified in Regulation 5.8 that arises during the reporting period, concerning Class III, Class AIMD or implantable Class IIb medical devices. The reporting period for the first report commences on the date of inclusion and is to be at least a period of six months but not more than 18 months ending on 1 October. For subsequent reports the reporting period is 12 months ending on 1 October.

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.