DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	11/30/2009 - 12/02/2009
	FEI NUMBER 3007139001

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edgar A. Otto, President

FIRM NAME	STREET ADDRESS
Hyperbaric America LLC	1902 7th Court North #A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Worth, FL 33461	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The device master record does not include or refer to the location of quality assurance procedures and specifications.

Firm lacked purchasing control, inspection, assembly, and installation procedures prior to November 2009. The firm attempted to install one Hyperbaric unit at a hospital in Florida in May 2009, but they could not get the unit to function correctly and it was not used with patients. On 11/4/2009, firm established Quality Control Manual Shop Assembly of Pressure Vessels Manual, but this does not include requirements for other components including but not limited to: plumbing; gurney; o-rings; flow masks; digital thermometer; timer; or fire retardant mattress.

OBSERVATION 2

Procedures to ensure that a device's design input requirements are appropriate and address its intended use, including user/patient needs, were not established, defined, documented, complete, and implemented.

Firm has made design changes such as change of pressure vessel material from (b) (4) to (b) (4) but has not considered that new 510(k) is required for significant changes.

OBSERVATION 3

The design history file was not established or maintained.

Firm lacks design history file for initial hyperbaric design except for drawings.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Richard K Vogel, Investigator Richard K. Vogel	DATE ISSUED 12/02/2009

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OBSERVATION 4

Design verification did not confirm that the design output meets the design input requirements.

Firm failed to verify accuracy of labeling in that it is stated in its brochure and website: "3 ATA Pressure Rated (Tested at 4.6 ATA)", but no testing at 4.6 ATA was done.

OBSERVATION 5

Procedures for management review are not documented, complete, and implemented.

Firm lacks management review procedure including the need to provide adequate resources for the Quality Assurance System.

OBSERVATION 6

Quality audits were not conducted to verify that the quality system is effective in fulfilling your quality system objectives.

OBSERVATION 7

Procedures for conducting quality audits were not established, defined, and documented.

OBSERVATION 8

Risk analysis was not performed.

OBSERVATION 9

Procedures to control the design process of the device were not established, defined, documented, and implemented.

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OBSERVATION 10

The procedures for implementing corrective and preventive actions were not established, defined, documented, and implemented.

OBSERVATION 11

Written MDR procedures have not been developed.

OBSERVATION 12

The device history record does not include acceptance records that demonstrate the device is manufactured in accordance with the device master record.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Promised to correct.	Observation 10:	Promised to correct.
Observation 11:	Promised to correct.	Observation 12:	Promised to correct.

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