DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2008

AOTI, Ltd.
% Mr. Robbie Walsh
Quality Assurance & Regulatory
Affairs
Qualtech House
Parkmore Business Park West
Galway, Ireland

Re: K080966
Trade/Device Name: Hyper-Box Topical Wound Oxygen System
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical oxygen chamber for extremeties
Regulatory Class: III
Product Code: KPJ
Dated: June 30, 2008
Received: July 3, 2008

Dear Mr. Walsh:

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

K080966

Indications for Use

510(k) Number:

Device Name: Hyper-Box Topical Wound Oxygen System

Indications for Use:

The AOTI Hyper-Box Topical Wound Oxygen System is intended to be used for the treatment of open acute or chronic wounds, such as;

- skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions
- decubitus ulcers
- amputations/infected stumps
- skin grafts
- burns
- frostbite

Prescription Use __X___ AND/OR Over-The-Counter-Use

(Part 21 CFR 801 Subpart D) (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)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080966