K070690

510(k) Summary for The Life Vessel™

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	Cottonwood Vessel Corp. 34 North Alamos Cottonwood, AZ 86326
Contact Person:	Miki Kolton Greenberg Traurig, LLP 800 Connectict Ave. NW, Suite 500 Washington, D.C. 20006
Summary Preparation Date:	March 9, 2007

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2. Names

Device Name:	The Life Vessel™
Classification Name:	Infrared Lamp Product Code: ILY

3. Predicate Devices

The Life Vessel™ is substantially equivalent to a combination of the Care Electronics, Inc. Dermillume Red HR1000 Lamp (K051681), the Quantum Devices, Inc. Quantum WARP 10 Light Delivery System (K032229), the Diomedics, Inc. Pain-X-2000 Models: 300, 600, 900, 1600, 2500 and 5700 (K982546), and the Light Force Therapy, Inc. Acubeam Super Nova, Dio (K022888).

4. Device Description

The Life Vessel™ is a chamber in which the patient lays flat under the treatment light source and positions the part of the body to be treated under the light source. The system is also used for non-medical relaxation applications and for these purposes includes music and sound components for relaxation.

5. Indications for Use

The Life Vessel™ is indicated to provide topical heating for the relaxation of muscles and relief of muscle spasms, temporary relief of minor muscle and joint aches, pains and stiffness, temporary relief of minor pain and stiffness associated with arthritis, and to temporarily increase local blood circulation.

6. Performance Data

Performance data was submitted which demonstrated that the system increases skin temperature to 40-45 degrees C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Cottonwood Vessel Corporation
% Ms. Miki Kolton
Greenberg Traurig, LLP
800 Connecticut Avenue, NW
Washington, DC 20006

Re: K070690
Trade/Device Name: Life Vessel
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: October 10, 2007
Received: October 10, 2007

Dear Ms. Kolton:

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 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark Melkerson
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070690

Device Name: The Life Vessel™

Indications For Use:

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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)

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

510(k) Number K070690