

GWR 510(k) Premarket Notification - O<sub>2</sub> Boot™

K971507

**Summary of Safety and Effectiveness**

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NOV - 7 1997

**Date summary was prepared:**

April 25, 1997

**Name(s) of the device:**

O<sub>2</sub> Boot™

**Identification of predicate device(s)**

The following are identified as predicate device to the O<sub>2</sub> Boot™:

OXYCURE™ Cushion. K831825

OXYCURE™ Boot. K840817

Topical Hyperbaric Oxygen Chamber. K861593

Topical Sacral Hyperbaric Oxygen Chamber. K920948

**Description of the device**

The GWR O<sub>2</sub> Boot™ is a Topical Oxygen Chamber for Extremities. It is composed of a flexible plastic film shaped into a large boot. At the open end of the device there is a layer of white fabric impregnated with an acrylic adhesive and is used to secure the boot to the patient being treated. There are two tubes that pass through the film; one is to inject the O<sub>2</sub> and the other contains a pressure relief valve that is set to maintain the proper pressure to inflate the boot, yet not over inflate the boot for treatment of the patient. In addition, plastic tubes are a part of the device and are used to transport the O<sub>2</sub> from the O<sub>2</sub> supply to the boot and create the oxygen chamber.

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The O<sub>2</sub> Boot™ is designed to encapsulate the whole leg or arm and therefore treat multiple wounds that could be present on the leg in diabetic or geriatric patients. In addition, it is a single use, single patient, disposable device.

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### **Intended Use**

The intended use of the O<sub>2</sub> Boot™ is to provide hyperbaric oxygen to open, chronic wounds as an adjunct therapy in wound management and treatment. Increasing the oxygen concentration above chronic open wounds with the use of this topical hyperbaric oxygen device, may promote the rate of healing and suppress bacterial growth.

### **Comparison of device characteristics to predicate**

The GWR O<sub>2</sub> Boot™ has the same technical characteristics as the predicate devices. It is almost exactly like the OXYCURE™ Boot marketed by Hospitak, Inc. The other predicates all have similar characteristics in that they are intended to deliver hyperbaric oxygen to open, chronic wounds in oxygen chambers for extremities. The method of delivery, indications for use and the device design is the same for the predicates and the O<sub>2</sub> Boot™. The difference between the devices is that the O<sub>2</sub> Boot™ is a single-use disposable device and the predicates are multiple use. The single-use characteristics eliminates the problem of transmission of disease from one patient to another or from one wound on the same patient to a new wound. The only reusable part is the tubing and it does not come in contact with the patient.

### **Non clinical testing**

The physical properties of the materials used to manufacture the O<sub>2</sub> Boot are tested by the suppliers to ensure they meet the specifications for the finished device. The testing are those established by ASTM. The materials that come in contact with the body are also tested using ISO methods for biocompatibility. All of the materials meet the specifications for the device. This is certified by the supplier of the materials to GWR Medical, L.L.P.

### **Conclusion**

It can be concluded based on the information provided that the GWR O<sub>2</sub> Boot is substantially equivalent to the predicate devices cited with respect to the indication for use, device design, mechanism of action and labeling.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**NOV - 7 1997**

Mr. Joseph R. Westwood  
V.P. Technology  
GWR Medical, L.L.P.  
124 Commons Court  
Chadds Ford, Pennsylvania 19317

Re: K971507  
Trade Name: O<sub>2</sub>Boot™  
Regulatory Class: III  
Product Code: KPJ  
Dated: August 8, 1997  
Received: August 14, 1997

Dear Mr. Westwood:

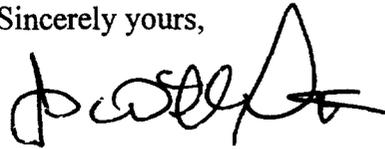
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



*fr* Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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**Indications for use**

**510(k) Number** K971507

None assigned as of this time

**Device Name**

O<sub>2</sub>Boot™

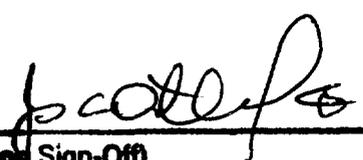
**Indications for Use**

Indications for the O<sub>2</sub>Boot are 1) skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions, 2) decubitus ulcers 3) amputations/infected stumps 4) skin grafts 5) burns 6) frostbite.

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (per 21 CFR 801.109)

Over-the Counter Use



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971507