



OCT 12 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Marie Marlow  
Vice President, Clinical and Regulatory Affairs  
HealthTronics, Inc.  
1841 West Oak Parkway, Suite A  
Marietta, Georgia 30062-9923

Re: P990086  
Device name: HealthTronics OssaTron®  
Filed: December 30, 1999  
Amended: March 22, April 5, May 11, May 17, August 3, September 7, and  
October 4, 2000

Dear Ms. Marlow:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the OssaTron. This device is indicated for use for performing extracorporeal shock wave (ESW) treatment in patients with chronic proximal plantar fasciitis that has failed to respond to conservative treatment. Chronic proximal plantar fasciitis is defined as pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity that has persisted for six months or more. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, you must conduct a postapproval study to further evaluate the long term safety of the OssaTron. Specifically the study is intended to evaluate the risk of neurological symptoms and mid-substance fascial tears on 300 patients followed for 12 weeks and using the most sensitive and specific objective measures like Semmes-Weinstein testing for sensory deficits,

physician's assessment for motor deficits, and physician's assessment for plantar fascia rupture. The information should be submitted on an annual basis. Results of the study must be reflected in the labeling (via a PMA supplement) when the study is completed. The final postapproval protocol must be submitted, as a PMA supplement, within 30 days from the date of this letter.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at <http://www.fda.gov/cdrh/pmat/pilotpmat.html> for further details.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

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If you have any questions concerning this approval order, please contact Sankar Basu, Ph.D. at (301) 594-1307.

Sincerely yours,

A handwritten signature in black ink that reads "Kimber Richter". The signature is written in a cursive, flowing style.

Kimber C. Richter, MD  
Deputy Director for Clinical  
and Review Policy  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure: Conditions of Approval