OssaTron - P990086

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	OssaTron
Manufacturer:	HealthTronics, Inc.
Address:	1841 West Oak Parkway, Suite A, Marietta, Georgia 30062-9923
Approval Date:	October 12, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990086a.pdf

What is it? The OssaTron is a shock wave generator used to treat chronic heel pain. The shock waves are created by a spark plug enclosed in a soft plastic dome filled with water. During treatment, the dome is placed closely against the heel so that the shock waves pass through the dome to the heel.

How does it work? Electrical charges sent through the water form a channel and evaporate water surrounding the device's electrodes. This creates a shockwave, which expands into the surrounding water. Treatment is performed as an outpatient procedure. A total of 1500 shocks are usually delivered.

When is it used? This is used for the treatment of chronic plantar fasciitis, a condition that causes chronic heel pain. The device is approved for adult patients who have had symptoms for a minimum of six months and have tried other standard methods of treatment.

What will it accomplish? HealthTronics studied 302 people with chronic heel pain who had tried conventional treatments unsuccessfully in the previous six months. Half were treated with the OssaTron; half received a sham treatment. 62% of the patients treated with the OssaTron reported some improvement in their heel pain; 48% of those treated with the sham said they experienced some improvement in pain.

When should it not be used? The device was not tested for bleeding disorder, pregnancy, and patients taking blood-thinning medication. If the device shows signs of any electrical or mechanical defect, e.g., faulty indicators, displays, or warnings, the device should not be used.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p990086.html

Other: http://jama.ama-assn.org/issues/v284n21/ffull/jfd00010-2.html

http://www.fda.gov/bbs/topics/ANSWERS/ANS01045.html

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