SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name:	Extracorporeal shock wave system
Device Trade Name:	HealthTronics OssaTron™
Applicant Name and Address:	HealthTronics, Inc. 1841 West Oak Parkway, Suite A Marietta, Georgia 30062
Date of Panel Recommendation:	July 20, 2000
Premarket Approval (PMA) Number:	P990086

Date of Notice of Approval to the Applicant: October 12, 2000

II. INDICATION FOR USE

The Healthtronics OssaTron™ 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 heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity that has persisted for six months or more.

III. CONTRAINDICATIONS

None known.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the device labeling.

V. DEVICE DESCRIPTION

Principles of Operation: The HealthTronics OssaTron™ ESW system utilizes electrohydraulic "spark gap" technology to generate shock waves: that is, a spark plug with two opposing electrodes is positioned under water such that an electrical discharge

is directed to the first focal point (F1) of an ellipsoid reflector. The electrodes are connected to a capacitor, which is charged to the maximal voltage and then abruptly discharged. The underwater discharge causes the explosive formation of a plasma channel and evaporation of the water surrounding the electrodes. The spherical shock wave that is released expands in the surrounding water and is reflected by the walls of the ellipsoid reflector. Because of the geometric properties of an ellipsoid reflector, all shock waves generated at F1 are reflected at its second focus (F2). Therefore, during an ESW procedure, the device shock head and the patient are carefully aligned and positioned such that target area to be treated is located at F2.

The OssaTron system incorporates all device components into a single transportable unit. The major components include the Therapy Head, the Control Cabinet, and the Control Console. A single-use electrode is placed in the Therapy Head for each treatment.

Therapy Head: The Therapy Head integrates the brass ellipsoid, the coupling membrane, the ELC 114 single-use electrode, the locating bow, and the dummy electrode. The brass ellipsoid houses the electrode, and reflects and focuses the shock waves. The Therapy Head is coupled to the patient via the water filled coupling membrane covering the ellipsoid. The ELC 114 electrode fits into the Therapy Head and extends into the brass ellipsoid. The electrode receives a high energy current from the Shock Wave Generator across the electrode tips, which produces the shock wave. A dummy electrode that is incapable of firing is provided for use only when transporting the device or when the device is stored. It is installed in the ellipsoid in the same fashion as an active electrode.

The Therapy Head includes an anti-collision device that halts shock wave generation and any mechanical movement of the device in the event of therapy head collision with the patient or table. A Locating Bow affixed to the Therapy Head allows for approximating the location of the shock wave therapy focus and aligning it with the desired target site during treatment. The Locating Bow can be rotated in 2 planes via the Control Console. The therapy head unit is connected to the Control Cabinet via an arm with 350 –degree rotation capability. The water supply and voltage cables attach to and rotate with the therapy arm.

Control Console: The Control Console includes a touch pad user interface with LED display and a hand held shock wave release button. The Control Console houses the two position key switch for turning power supply to the device on and off. Touch keys are provided for setting the desired shock wave energy (i.e., capacitor charge voltage in kV), and the frequency of shock wave delivery (Hz). The Control Console display shows these settings along with the total number of shocks delivered per procedure. Movement of the Therapy Head and the locating bow are also driven from the Control Console.

Control Cabinet: The Control Cabinet is the main body of the device. It connects to standard hospital main 120VAC single phase electrical power supply. The Control Cabinet is mounted on a locking wheelbase and incorporates 6 subcomponents: the charging unit, the shock wave generator, the electric module, the water supply unit, the water valve unit, and the motor drive units.

The charging unit delivers the high voltage to the shock wave generator, which in turn triggers transformers that discharge high-voltage energy across the electrode tips. The electric module is where power connections are made; it supports and controls most of the high and low power supplies to the system components. The water supply unit contains a water tank, a safety thermostat for temperature control, a desalination unit to set conductivity, and a small circulation pump and provides conditioning, de-gassing, and de-ionizing capabilities. The water valve unit allows pressure control for setting the coupling pressure during treatment, and for emptying and filling the therapy head following electrode change. The Motor drive units enable rotation of the Therapy arm and Locating Bow, and movement of the Control Cabinet on the wheelbase.

VI. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The adverse events that occurred during the clinical study are listed under the Part X, Section E, Item 5, titled, "Primary Safety Measurements".

The adverse effects observed during ESW treatment with the OssaTron™ include:

- Pain during the ESW treatment;
- Localized numbness, tingling or decreased sensation in the foot or at the site of shock wave delivery;
- Local subcutaneous hematoma, bruising, or petechial bleeding in the foot or at the treatment site; and
- Rupture of plantar fascia.

Other potential adverse events may include:

- Misdirection of ESW energy to a major nerve or blood vessel, resulting in injury;
- Anesthesia complications, including allergic reactions to local or regional anesthetic agents

VII. ALTERNATE PRACTICES OR PROCEDURES

For those patients who do not respond to conservative treatment and who seek definitive treatment for this disorder, surgical options include endoscopic plantar fasciotomy or open planter fascia release.

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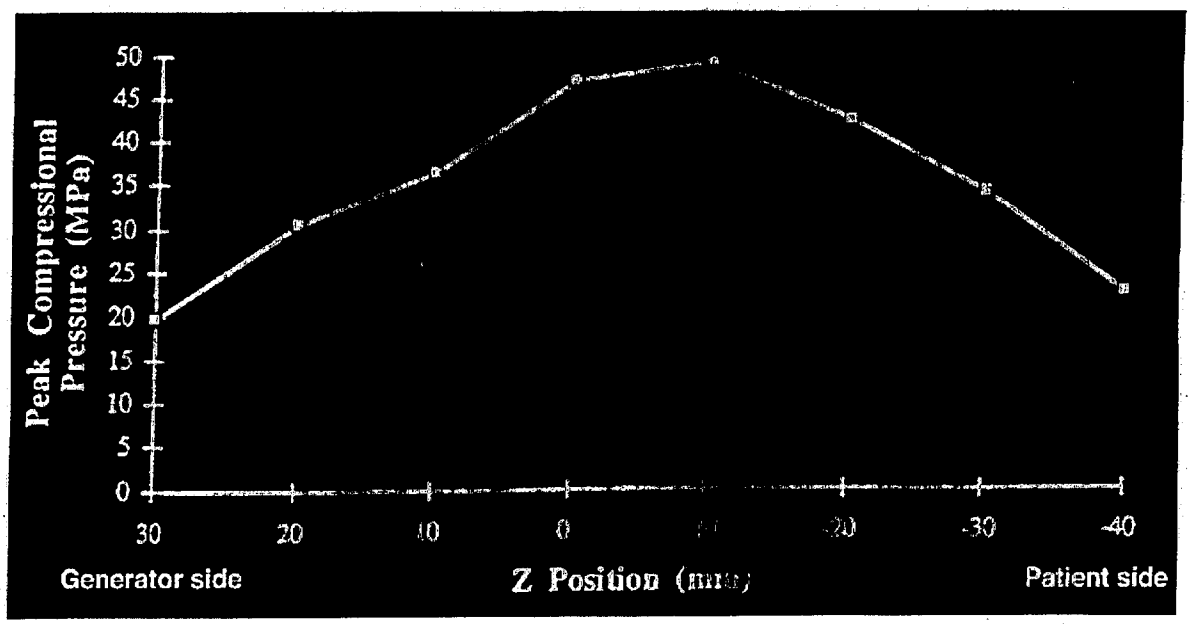
VIII. MARKETING HISTORY

The OssaTron™ has been commercially distributed in worldwide markets outside of the United States since August, 1994. The OssaTron™ system has never been withdrawn from marketing for any reason related to safety or effectiveness of the device.

IX. SUMMARY OF PRECLINICAL TESTING

Shock wave characterization: Shock wave output from the OssaTron™ was characterized according to the draft FDA guidance, "Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements" (January 18, 1991). Mean peak compressional pressure was 49.4 + 6.3 MPa; average rise time was 33 nanoseconds (ns) and average pulse width was 280 ns. The following figure shows peak compressional and rarefactional pressure as a function of generator voltage setting.



Electromagnetic compatibility: Electromagnetic compatibility of the OssaTron™ was tested and determined to be in compliance with IEC 601-1-1 and IEC 601-2-3.

Electrode testing: Sample OssaTron™ electrodes were tested to demonstrate the reliability of shock wave delivery at 18kV, 23kV, and 28kV. "Reliability" is defined as consistent shock wave delivery with each trigger impulse (i.e., no misfires). The electrodes were found to be reliable from a minimum of 1650 shocks delivered at 18 kV through 2750 shocks delivered at 28 kV.

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X. SUMMARY OF CLINICAL STUDIES

A. Study Design

The clinical study of the OssaTron™ was a multicenter, randomized, sham-controlled clinical trial to determine the safety and effectiveness of ESW treatment for chronic proximal plantar fasciitis. The study protocol was approved for a total enrollment of 350 subjects, including 300 subjects randomized to either active ESW treatment or sham treatment with the OssaTron™ and 50 nonrandomized subjects to allow each investigator to complete training requirements for performing the OssaTron™ procedure. The patients were followed up at 4, 8, and 12 weeks after the treatment.

A minimum of two investigators participated in the study at each site so that one investigator could serve as the blinded evaluator for baseline and post treatment follow up visits. The non-blinded investigator performed the study procedures as follows: Each study subject received a local anesthetic or an ankle block prior to the study procedure. The affected leg was then draped from the view of the study subject. Each subject assigned to active treatment then underwent an ESW procedure with a total of 1500 shocks delivered at a power setting of 18kV. The average active treatment time was 17 minutes. For subjects assigned to sham treatment, a Styrofoam block was placed against the coupling membrane of the shock head to absorb the shock waves. A fluid-filled IV bag was then placed between the Styrofoam block and the subject's heel to mimic the feel of the coupling membrane, and 1500 shocks were then delivered at 18 kV.

B. Inclusion and Exclusion Criteria

Enrollment was limited to patients with the following criteria:

- proximal plantar fasciitis (recalcitrant heel pain) persisting for at least 6 months;
- failure to respond to at least three attempts at conservative treatment: two prior courses of non-invasive treatment, including physical therapy (e.g., stretching exercises) and the use of an orthotic device; and one prior course of pharmacological treatment such as NSAID's or cortisone injections;
- investigator assessment of pain at the origin of the plantar fascia on the medial calcaneal tuberosity $\geq$ 5.0 cm on a 10 cm Visual Analog Scale (VAS);
- subject self-assessment of pain after the first five minutes of walking in the morning $\geq$ 5.0 cm on a 10 cm VAS;
- female subjects must not be pregnant;
- other causes for heel pain have been ruled out, such as vascular insufficiency or neuropathy of the lower extremities;
- concomitant pathology has been ruled out, including severe osteoarthritis; rheumatoid arthritis, osteoporosis; metabolic disorders; malignancies; Paget's

disease; and acute, subacute or chronic osteomyelitis or systemic infection; or fracture of the affected foot or ankle; and

- 21 years of age or older to assure all subjects would be skeletally mature.

C. Evaluation Methods

1. Investigator Assessment:

The investigator blinded to randomization assignment assessed the subject's heel pain by applying pressure on the affected heel at the origin of the plantar fascia on the medial calcaneal tuberosity. The investigators used a pressure sensor to record the amount of pressure applied to elicit the baseline response, and thereafter to apply the same amount of pressure at each follow up assessment to assure consistency in this evaluation. To be eligible for study participation, a subject must report a pain score of 5.0 or greater on 10.0 cm VAS during the investigator's initial assessment.

2. Subject Self-Assessment of Pain:

Each subject was asked to provide a self-assessment of the amount of pain experienced during the first few minutes of walking in the morning, reported according to a 10 cm VAS. To meet study inclusion criteria, the subject's initial VAS must have been moderate to severe, i.e., 5.0 cm or greater on a 10 cm VAS.

D. Primary Effectiveness Measurements

The investigator who was blinded to randomization assignment determined the initial "success/fail" status for each study subject, who must meet all 4 of the following criteria in order for an overall status of "success" to be assigned at the 12 week follow-up visit.

1. Investigator's assessment of heel pain:

A minimum 50% improvement over baseline, and a score no greater than 4.0 on VAS.

2. Subject's self-assessment of pain upon first few minutes of walking in the morning:

A minimum 50% improvement over baseline with a score no greater than 4.0 on VAS was required for a status of "success" to be assigned for this parameter.

3. Subject's self-assessment of activity level, measured by the distance and time the subject is able to walk without heel pain:

The subject must demonstrate an improvement of 1 point on a 5 point scale OR maintain a baseline score of 0 or 1 (no limitation / minor limitation) at the 12 week follow up visit for a status of "success" to be assigned for this parameter.

4. Use of pain medications:

The subject must not be taking any pain medications for heel pain at the 12 week follow up visit for a status of "success" to be assigned for this parameter.

E. Data Analysis and Results

1. Study Enrollment

A total of 314 subjects were enrolled in the study at the time the database was closed. Of these 314, 302 had completed the study treatment by the time of database closure, including 42 nonrandomized subjects enrolled to accomplish investigator training requirements and 260 randomized subjects. Twenty-one subjects had not completed the 12 week follow-up at that time.

Five of the 302 subjects (1.7%) withdrew from the study or were lost to follow up prior to the 12 week follow up visit. One of the five subjects lost to follow-up was a nonrandomized subject, and the remaining 4 were randomized subjects. A total of 235 randomized and 41 nonrandomized subjects were assigned a success/fail status based on 12 week follow-up findings.

Table 1 summarizes the 12 week follow up status for all study subjects.

Table 1: Study Participation Status
Follow Up at 12-Weeks

	Active Treatment Subjects	Placebo Treatment Subjects	Nonrandomized Subjects	TOTAL
Total Subjects Treated	130	130	42	302
Subjects less than 12 weeks since treatment	10	11	0	21
Total Subjects Eligible for 12 Week Follow Up	120	119	42	281
Total lost to follow up or withdrawn	1	3	1	5
Total Subjects with 12 Week Status	119 (99.2%)	116 (97.5%)	41 (97.6%)	276 (98.2%)

2. Gender Analysis:

The study population was predominantly female (65.9%), and subjects' ages at the time of study enrollment ranged from 20 years to 79 years, mean 49.62. Subjects were predominantly Caucasian. Although the study population included more females than males (2:1) the analysis of the results did not demonstrate that the treatment outcomes both in terms of effectiveness or adverse events were biased by gender.

3. Duration of Symptoms at Baseline:

The study protocol required that each subject must have had symptoms of proximal plantar fasciitis for at least six months prior to study enrollment. Table 2 shows mean duration of symptoms for subjects randomized to active treatment was 968 days (2.65 years), range 6 months to 13 years. For subjects randomized to sham treatment, the mean duration of symptoms was 1078 days (2.95 years), range 6 months to 18 years. For the nonrandomized subjects, the mean was 943 days (2.58 years), range 4.6 months to 10 years.

Table 2: Duration of Symptoms (in days)

	N	Mean (StDev)	Median	Range
Active Treatment	130	967.83 (975.85)	567	183-4910
Placebo Treatment	129*	1078.10 (1190.80)	575	180-6629
Nonrandomized	42	943.26 (940.96)	548	137-3912

*Complete baseline data is unavailable for one subject randomized to sham treatment.

4. Effectiveness Analysis

a. Investigator Assessment:

The subjects randomized to active ESW treatment improved from a mean baseline VAS score of 7.68 to 3.13 at 12 weeks as has been shown in Table 3. The median 12 week VAS score was 1.90. Seventy-four of the 119 subjects (62.2%) met the success criteria for this parameter. The subjects randomized to placebo treatment improved from a mean baseline score VAS of 7.87 to 4.37 at 12 weeks. The median 12 week VAS score was 4.70. Fifty-one of the 116 subjects (43.97%) met the success criteria (minimum 50% improvement and VAS score of 4.0 or less) for this parameter. Tables 3 through 7 show data with randomized subjects only.

Table 3: Investigator Assessment - Baseline through 12 Weeks

		Baseline	4 weeks	8 weeks	12 weeks
Active ESW Treatment*	N	119	107	98	118
	mean	7.68	4.80	3.83	3.13
	(StD)	(1.37)	(3.31)	(3.01)	(3.17)
	median	7.80	4.70	4.15	1.90
	range	3.10 – 10.00	0.00 – 10.00	0.00 – 10.00	0.00 – 10.00
Placebo Treatment**	N	115	104	91	116
	mean	7.86	6.01	5.11	4.37
	(StD)	(1.33)	(2.92)	(3.14)	(3.23)
	median	8.12	6.90	5.50	4.70
	range	5.20 – 10.00	0.00 – 10.00	0.00 – 10.00	0.00 – 10.00

*Excludes one subject lost to follow up prior to 12 weeks
**Excludes three subjects lost to follow up prior to 12 weeks

b. Subject Self-Assessment of Pain:

At each study visit subjects were asked to report the amount of pain experienced over the past week during the first few minutes of walking in the morning. The subject recorded the response on the 10 cm VAS scale. According to the Table 4 the subjects randomized to active ESW treatment improved from a mean baseline VAS score of 8.02 to 3.48 at 12 weeks. The median 12 week VAS score was 2.60. Seventy-one of the 119 subjects (59.7%) met the success criteria (minimum 50% improvement and VAS score of 4.0 or less) for this parameter.

The subjects randomized to placebo treatment improved from a mean baseline VAS score of 8.20 to 4.20 at 12 weeks. The median 12 week

VAS score was 4.05. Fifty-six of the 116 subjects (48.3%) met the success criteria (minimum 50% improvement and VAS score of 4.0 or less) for this parameter.

Table 4: Subject Self-Assessment - Pain
Baseline through 12 Weeks

		Baseline	4 weeks	8 weeks	12 weeks
Active Treatment*	*N* mean (StD) median range	119 8.027 (1.37) 8.10 4.00 – 10.00	108 4.47 (2.84) 4.70 0.00 – 10.00	98 4.05 (2.89) 4.25 0.00 – 10.00	118 3.48 (3.11) 2.60 0.00 – 9.90
Placebo Treatment**	*N* mean (StD) median range	115 8.14 (1.33) 8.20 5.00 – 10.00	103 5.42 (2.74) 5.80 0.00 – 10.00	91 4.61 (2.86) 4.80 0.00 – 10.00	114 4.18 (3.04) 4.05 0.00 – 10.00

*Excludes one subject lost to follow up prior to 12 weeks
**Excludes three subjects lost to follow up prior to 12 weeks

c. Subject Self-Assessment of Activity:

Each subject was asked to provide a self-assessment of his or her ability to walk before pain in the affected heel severely limited his or her ability to walk any further, measured by time and by distance. Scores for both measurements were combined to assign a value to the subject's self-assessment of activity as reported in Table 5.

Distance Walked without Pain: This self-assessment was reported according to a 5 point scale: 0 = No limitation due to heel pain; 1 = able to walk 6 to 10 blocks, 2 = able to walk 4 to 6 blocks, 3 = able to walk 1 to 3 blocks, 4 = able to walk less than 1 block. Subjects receiving active ESW treatment improved from a mean baseline score of 3.49 to 1.72 at 12 weeks. Median 12 week score was 1.00. Subjects receiving placebo treatment improved from a mean baseline score of 3.53 to 1.88 at 12 weeks. Median 12 week score was 2.00.

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Table 5: Subject Self-Assessment - Activity
Distance Walked without Pain, Baseline through 12 Weeks

		Baseline	4 weeks	8 weeks	12 weeks
Active Treatment*	*N*	119	109	98	118
	Mean	3.49 (0.50)	2.06 (1.50)	2.02 (1.45)	1.72 (1.47)
	(StD)	3.00	2.00	2.00	1.00
	Median	3.00 –	0.00 –	0.00 –	0.00 –
	Range	4.00	4.00	4.00	4.00
Placebo Treatment**	*N*	115	106	92	114
	Mean	3.53 (0.50)	2.18 (1.37)	2.15 (1.43)	1.88 (1.44)
	(StD)	4.00	2.50	3.00	2.00
	Median	3.00 –	0.00 –	0.00 –	0.00 –
	Range	4.00	4.00	4.00	4.00

*Excludes one subject lost to follow up prior to 12 weeks
**Excludes three subjects lost to follow up prior to 12 weeks

Overall, 85/119 (71.42%) active treatment subjects met success criteria for the combined activity self-assessments, and 78/116 (67.24%) placebo treatment subjects met success criteria.

d. Use of Pain Medications:

Each subject was asked to report the medications he or she was taking for pain at the initial study evaluation visit, and thereafter to keep track of all medications taken for pain throughout the course of study participation. The use of pain medications was then classified according to the frequency of use: chronic, frequent, occasional, rare, or none. Exact definitions for these classifications were provided in the study protocol. In order to be assigned a status "success" for this parameter, the study protocol required that the subject could be taking no pain medications at the time of the 12 week follow up visit. The results are shown under Table 6.

At baseline, 106/119 (89.1%) active treatment subjects were routinely taking medication for heel pain. This had been reduced to 36/119 (30.3%) by the 12 week visit. Eighty-three of 119 subjects followed to 12 weeks (69.7%) met the success criteria for this parameter. At baseline, 106/119 (89.1%) active treatment subjects were routinely taking medication for heel pain. This had been reduced to 36/119 (30.3%) by the 12 week visit. Eighty-three of 119 subjects followed to 12 weeks (69.7%) met the success criteria for this parameter.

Table 6: Medication Requirements At Each Follow Up Visit

	Baseline	Medication Requirement	4 weeks	8 weeks	12 weeks
Active Treatment * ***N*=119**	None: 13 NSAID's: 68 Other: 38	None Rare Occasional Frequent Chronic	47 17 18 18 17	51 14 5 7 20	74 9 8 9 19
Placebo Treatment** ***N*=116**	None: 18 NSAID's: 53 Other: 45	None Rare Occasional Frequent Chronic	46 10 18 7 24	47 7 13 6 19	68 15 8 6 19

*Excludes one subject lost to follow up prior to 12 weeks
**Excludes three subjects lost to follow up prior to 12 weeks

e. Overall Success/Fail Status:

The analyses showed that a single ESW procedure with the OssaTron™ is an effective treatment for chronic proximal plantar fasciitis when compared to placebo treatment at 12 weeks. Of the 119 subjects followed to 12 weeks after an active OssaTron™ ESW treatment, 56 (47.1%) met all 4 success criteria, compared to 35 of 116 placebo treated subjects (30.2%) who met all 4 criteria, a difference that is significant at a p level of 0.008.

The majority of the treatment effect was observed in the blinded evaluator's assessment of heel pain. The subjects' self-assessments of pain during the first few minutes of walking in the morning showed less treatment difference. The subjects' self-assessments of activity level and use of pain medications did not indicate large treatment differences through 12 weeks, and were not statistically different. The active treatment subjects showed greater improvement in SF-36 scores than did placebo subjects. However, none of the primary or secondary outcome measurements demonstrated treatment differences as pronounced as the investigator assessment [Table 7].

Table 7: 12 Week Response to Treatment
All Components of Success

Response			
Measure	**Active OssaTron™ ESW Treatment* N=119**	**Placebo Treatment** N=116**	***p* Value[1]**
Investigator Assessment	62.2%	44%	0.005
Self Assessment, Pain in AM	60%	48%	0.080
Activity Level	71%	67%	0.486
Medication Use	70%	65%	0.406
All Components	47%	30%	0.008

[1] Pearson X^2
*Excludes one subject lost to follow up prior to 12 weeks
**Excludes three subjects lost to follow up prior to 12 weeks

Duration of symptoms was significantly associated with success (p=0.005): subjects with shorter duration of symptoms had higher response rates, and the absolute difference in success rates between the two subject groups was similar in magnitude. Further, baseline heel pain was also significantly associated with success, with the overall association of treatment and success still significant (p=0.015) after adjusting for heel pain.

5. Primary Safety Measurements

a. Complications and Adverse Events

A total of 38 complications or adverse events were reported for the 302 treated subjects participating in this study. These 302 subjects received 273 active ESW treatments and 130 placebo treatments. An additional active ESW procedure was attempted but was interrupted by a device failure before the subject had received more than 10 shocks.

The overall complication rate for any subject receiving an active ESW treatment was 12%, including both device- or procedure-related events and events unrelated to the study procedure.

The most commonly reported procedure-related complications for all three study groups were post-treatment pain and mild neurological symptoms (numbness, tingling) in the treated foot. Pain was reported following 4/273 (1.5%) of the active ESW procedures and 4/130 (3.1%) of the placebo procedures. Localized neurological symptoms were reported

following 6/273 (2.2%) active ESW procedures and 1/130 (0.1%) placebo procedures. Two subjects receiving active ESW treatment (0.1%) sustained midsubstance plantar fascia tears during the course of study participation.

Two late procedure-related complications occurred, including an exacerbation of heel pain at 6 months in a nonrandomized subject, and localized tingling at the site of the ankle block injection at 12 weeks in an active treatment subject. Both of these late complications resolved spontaneously without intervention.

The adverse event data in the Table 8 have been grouped according to the following classifications:

Device: Device failure or malfunction.
Local: Bruising, edema, or increased pain at the treatment site.
Neuro: Post-treatment nerve irritation, tingling, numbness, or decreased sensation of the treated foot or ankle.
Other: Includes neck pain, spinal symptoms, low back pain, neck or back injury, disc symptoms, myocardial infarction, pacemaker implantation, trochanteric bursitis, knee pain, knee arthroscopy, groin injury, shoulder surgery, and colon surgery.
Pain: Post-treatment foot or ankle pain more intense or otherwise differing from pretreatment pain.
Tear: Midsubstance ruptures of the plantar fascia.
Tendonitis: Achilles or posterior tibial tendonitis.

Table 8 : Complications or Adverse Events
All Study Subjects

Event	Active Treatment Group (n=130)	Nonrandomized Group (n=42)	Placebo Treatment Group (n=130)		TOTAL (n=302)
			Retreatment*	Placebo	
Procedure related					
Device	1	0	0	0	1
Local	1	1	0	0	2
Neuro	5	1	0	1	7
Pain	1	2	1	4	8
Tear	2	0	0	0	2
Subtotal	**10**	**4**	**1**	**5**	**20**
Not procedure related					
Other	7	1	1	6	15
Tendonitis	1	0	0	2	3
Subtotal	**8**	**1**	**1**	**8**	**18**
TOTAL	**18**	**5**	**2**	**13**	**38**
Total events: Active treatment Placebo treatment	**25**			**13**	**38**

*Includes placebo treatment patients who chose to have active treatment after completing 12 weeks follow up

XI. CONCLUSIONS DRAWN FROM THE STUDY

The preclinical and clinical data provides reasonable assurance that the HealthTronics Ossatron™ device is safe and effective when used in accordance with the device labeling.

XII. PANEL RECOMMENDATION

At an advisory meeting held on July 20, 2000, the Orthopedics and Rehabilitation Devices Panel recommended that the PMA for the HealthTronics Ossatron™ be approved.

XIII. CDRH DECISION

Approval order for this PMA was issued on October 12, 2000 with the requirement that the company must conduct a post-approval study to investigate the plantar fascial tears and neurological symptoms developed during the clinical study in some patients as has been reported in the PMA.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See labeling.

Hazard to health from use of the device: See Warnings, Precautions, and Adverse Events Section in the labeling.

Conditions of Approval: See approval order.