SUMMARY OF SAFETY AND EFFECTIVENESS

I General Information

Device Generic Name:	Orthopedic Extracorporeal Shock Wave Therapy Device
Device Trade Name:	EMS Swiss DolorClast®
Applicant Name and Address:	Electro Medical Systems (EMS) S.A. Chemin de la Vuarpillière 31 CH – 1260 Nyon, Switzerland
PMA Number:	P050004
Date of Panel Recommendation:	None
Date of Notice of Approval to Applicant:	May 8, 2007

II Indications for Use

The EMS Swiss DolorClast® is a non-surgical alternative for the treatment of chronic proximal plantar fasciitis for patients 18 years of age or older with symptoms for 6 months or more and a history of unsuccessful conservative therapy. Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity.

III Contraindications

Use of the EMS Swiss DolorClast® is contraindicated in the following situations:

1. Over or near bone growth center until bone growth is complete
2. When a malignant disease is known to be present in or near the treatment area
3 Infection in the area to be treated
4. Over ischemic tissue in individuals with vascular disease
5. Patient has a coagulation disorder or if taking anti-coagulant medications
6. Patient has a prosthetic device in the area to be treated.

IV Warnings and Precautions

The warnings and precautions for use of the EMS Swiss DolorClast® for the treatment of chronic proximal plantar fasciitis can be found in the device labeling.

V Device Description

The EMS Swiss DolorClast® consists of a control unit and a handpiece. An applicator is mounted onto the distal end of handpiece, fixed by a screw cap. A pressure pulse from the compressed air supply causes a projectile within the handpiece to be driven forward and to strike the inner surface of the applicator probe. The impact generates a shock wave in the applicator that travels to the distal surface of the probe and is transferred to the treatment target by direct contact. The shock wave propagates radially into the tissue from the point of contact. Thus, the device has no "focusing" characteristics, per se, because the maximum energy is directly at the coupling point on the skin surface, targeting the treatment areas of interest that are close to the skin. The maximum possible energy flux density (ED_+^{max}) is 0.18 mJ/mm^2.

The EMS Swiss DolorClast® system consists of the following components:

Control unit (100 – 240 VAC / 50 Hz – 60 Hz)

Handpiece set with a 15 mm applicator

Foot pedal

Coupling gel bottle

Power supply cord (hospital grade)

Compressed air tube

Component case

An air compressor and a mobile cart are provided as optional accessories.

The control unit houses the power supply, impulse circuitry, and pneumatic switches used to generate the pressure impulses to the handpiece. The pressure regulator controls the external compressed air supply, which is preset at 5 to 6 bar, providing a user-adjustable driving pressure of 0 to 4 bar for the handpiece. An increase in driving pressure results in an increase in projectile speed in the handpiece and a corresponding increase in applied energy to the tissue. The impulse frequency can be set from 1 to 15 Hz. Other user-selectable treatment parameters include the operating mode (single versus multiple impulses) and

number of impulses (1 to 9999). Treatment parameters (impulse pressure, impulse frequency and number of impulses) are displayed on the front panel of the pressure regulator/control unit. The device incorporates a microprocessor for control of the operating parameters.

VI Alternative Practices and Procedures

Chronic proximal plantar fasciitis is generally treated conservatively with a variety of pharmacological and nonpharmacological therapies. Pharmacological therapies may include OTC or prescription analgesics or non-steroidal anti-inflammatory agents (NSAIDs), local anesthetic injections or local corticosteroid injections. Nonpharmacological therapies may include physical therapy such as ice, heat or ultrasound; physiotherapy such as massage and stretching; orthotics, heel pads, shoe modifications, taping, night splints, immobilization, or casting. Current nonconservative treatments for chronic proximal plantar fasciitis include shockwave therapy with another commercially available shock wave therapy device or surgery.

VII Marketing History

The EMS Swiss DolorClast® received the CE Mark in July 1999. Since that time, approval to market the EMS Swiss DolorClast® has been granted in Brazil, Canada, Switzerland, the Czech Republic, Hungary, Russia, China, Korea, and Australia. The EMS Swiss DolorClast® is also commercially available in Hong Kong, where government marketing approval is not required. The EMS Swiss DolorClast® has not been withdrawn from marketing for any reason related to safety and effectiveness of the device in any country.

VIII Adverse Effects of the Device on Health

During the EMS Swiss DolorClast® clinical study, a total of 73 non-serious adverse events were reported during the 12 week follow-up period in 41 of the 129 patients (31.8%) receiving active treatment. Of these reports, 23 adverse events in 16 patients were considered to be not device related and 50 adverse events in 33 patients were considered to be device related. Eight patients reported both device related and non-device related adverse events.

In the placebo group, a total of 36 adverse events were reported in 27 of the 122 patients (22.1%) during the 12 week follow-up period. Of these reports, 25 adverse events in 19 patients were considered to be not device related, and 11 adverse events in 10 patients were considered to be device related. Two of these patients reported both device related and non-device related adverse events.

Table 1 summarizes the adverse events that were considered to be related to the device. The most common adverse event associated with use of the EMS Swiss DolorClast® is pain or discomfort during treatment. This side effect was noted by 23% of the patients treated with the EMS Swiss DolorClast® in the clinical study, but all patients except for one were able to complete their treatments without any anesthesia. In the majority of cases the duration of treatment pain was reported to be a maximum of less than 10 minutes.

Table 1: Summary of Device Related Adverse Events, Safety Population (n=251) at Visit 7 (12-Week Follow-up)

Event	ESWT Group (N=129)			Placebo Group (N=122)		
	# Events	# Subjects	% Total Subjects	# Events	# Subjects	% Total Subjects
Pain or discomfort during treatment	43	30[1]	23.26%	5	5	4.10%
Pain post-treatment	5	5[2]	3.88%	3	3	2.46%
Skin reddening	1	1[3]	0.78%	1	1	0.82%
Swelling and pain post-treatment	1	1	0.78%	1	1	0.82%
Numbness post-treatment	0	0	0%	1	1	0.82%

[1]Twenty subjects with pain during one treatment session, seven during two sessions, and three during three sessions
[2]Three subjects also reported pain during treatment.
[3]This subject also reported pain during treatment.

In the active ESWT treated group, a total of 23 non-device related adverse events were reported in 16 of the 129 patients (12.4%). These were as follows: wasp sting (1), common cold disease (3), cough (1), sinusitis (2), headache (6), body aches (1), pain of the hip (1), toe (1) or neck (1), intermittent back pain of unknown etiology (1), aggravated neuroma (1), tinnitus (1), occasional knee weakness due to knee injury (1), developing tendonitis (1), and heart murmur (1).

In the placebo group, there were a total of 25 non-device related adverse events reported in 19 of the 122 patients (15.6%). These reports were as follows: gastric ulcer (1), upset stomach (2), irregular heart "movement" (1), pain long after treatment end in heel(1)/right shoulder (1)/body aches (1), infection of nose, ear and throat (1), fracture of the toe (right foot) (1), pain and swelling of left knee

(1), acute nausea (1), adductor-strain (1), headache (10), common cold disease (2) and congestion (1).

Only six additional adverse events in five patients (1 in the active ESWT treated group and four in the placebo group) were reported during the 6-month and 12-month follow-up period. All of these reports were considered to be not related to the device. There was one report of ischiatic pain plus lumbar back pain in one patient in the active ESWT treated group. There were five non-device related adverse event reports in four patients in the placebo treated group. These were as follows: lateral right foot pain along metatarsus (1), acute nausea (1), teeth inflammation (1), zoster neuralgia (1), and umbilical hernia (1).

Other potential adverse events that have not been observed in clinical studies of the EMS Swiss DolorClast® may include:

- Bruising
- Rupture of the plantar fascia (tissue along the bottom of the foot)
- Temporary or permanent damage to the blood vessels
- Petechia
- Temporary or permanent nerve damage causing hypesthesia or paresphesia
- Hematoma
- Tendon Rupture

IX Summary of Non-Clinical Testing

Shock Wave Characterization

Acoustic output measurements were performed to measure the maximum shock wave output of the EMS Swiss DolorClast®. In addition, other shock wave performance characteristics as specified in FDA's *Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi*, were measured where applicable. The experimental setup complied with the requirements of IEC 61846 (1998): Ultrasonics - Pressure pulse lithotripters - Characteristics of fields. Measurements were made using a fiberoptic hydrophone, at maximum pressure setting, in a container of degassed water with the hydrophone positioned within an accuracy of 100 μm. Pressure signals from the hydrophone amplifier were

recorded using an oscilloscope through an average value calculation of 20 single impulses. Results are given in Table 2.

Table 2: Shockwave Characteristics

Physical quantities	Symbol	Results
Peak positive acoustic pressure	P_+^{max}	11.92 MPa
Peak negative acoustic pressure	P_-^{max}	- 5.86 MPa
Rise time	t_r	3 µs
Compressional impulse duration	t_p	2.5 µs
Pressure decrease time	-	0.91 µs
Max. pos. Energy flux density	ED_+^{max}	0.18 mJ/mm^2
Maximum focal width (-6dB focal size x, y)	$fx_{-6\,dB}$	$8.0 \cdot 10^{-3}$ m
Orthogonal focal width (-6dB focal size z)	$fy_{-6\,dB}$	$8.0 \cdot 10^{-3}$ m
Focal extent	$fz_{-6\,dB}$	$8.0 \cdot 10^{-3}$m
Focal volume	$fv_{-6\,dB}$	$268 \cdot 10^{-9}$ m^3
Distance between the focus and target location	-	N.A. (not a focused device)
Derived focal acoustic impulse energy	$E_{-6\,dB}$	5.4 mJ
Derived acoustic impulse energy	E	8.6 mJ

Handpiece Longevity

The longevity of the handpiece was validated to have a lifetime in excess of 500,000 impulses (equivalent to about 250 uses). Four handpieces were tested until failure or 1,000,000 impulses, whichever came first. One blocked after 500,000 impulses, another after 800,000 impulses and the remaining two were still functioning at 1,000,000 impulses.

Electrical Safety and Electromagnetic Interference Testing

The EMS Swiss DolorClast® was tested by Montena, a test laboratory certified by the Swiss Federal Office of Metrology, and found to be in conformance with the electrical safety requirements of IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, and the electromagnetic compatibility requirements of IEC 60601-1-2: Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests.

Software Verification and Validation

Software verification and validation testing was conducted in accordance with the EMS Swiss DolorClast® Software Verfication and Validation Plan and the device was found to meet all tests requirements, with no known unresolved anomalies remaining.

Biocompatibility Testing

Biocompatibility testing was conducted on the applicator, the only portion of the EMS Swiss DolorClast® intended to come in contact with the patient. Testing for in vitro cytotoxicity, sensitization, and intracutaneous reactivity was conducted in accordance with the applicable requirements of ISO 10993: Biological evaluation of medical devices - Part 1: Evaluation and Testing, and as specified in FDA's guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices* (May 1, 1995) and in accordance with the principles of Good Laboratory Practice. All test criteria were successfully met.

In addition, the manufacturer of the contact gel conducted a human patch test for primary skin irritation and allergic hypersensitivity to the gel. Thirty (30) volunteer subjects with no visible skin diseases and no known allergic hypersensitivities were tested for 24 hours and examined at patch removal and at 48 and 72 hours after removal. There was no evidence of primary irritation or allergic hypersensitivity in any of the subjects.

X. Summary of Clinical Investigations

Study Design

A multicenter, randomized, placebo-controlled, prospective, double blind clinical study was conducted to assess the safety and effectiveness of the EMS Swiss DolorClast® when used to treat unsuccessful conservatively treated subjects with symptoms of chronic proximal plantar fasciitis. A total of 251 subjects were randomized with a 1:1 allocation ratio to one of two groups: a group receiving ESWT with the EMS Swiss DolorClast® and a control group receiving a sham treatment. The study was conducted at eight clinical sites: three in the United States and five in Germany. For the purpose of this study, chronic proximal plantar fasciitis was defined as painful tenderness localized at the inferomedial aspect of the calcaneal tuberosity close to the insertion area of the plantar fascia that had persisted for at least 6 months prior to study enrollment.

Subject Eligibility

Subjects were required to meet the following eligibility criteria in order to be enrolled into the study:

Inclusion Criteria

1. Age greater than 18 years
2. Ability of subject or legal respondent to give written informed consent after being told of the potential benefits and risks of participating in the study
3. Signed informed consent
4. Diagnosis of painful heel syndrome (i.e., chronic proximal plantar fasciitis) proven by clinical examination
5. Six months of unsuccessful conservative treatment i.e., have undergone at least 2 unsuccessful non-pharmacological treatments and at least 2 unsuccessful pharmacological treatments. The following conservative treatments may have been completed as single, combined or consecutive treatments:

   Non-pharmacological treatments

   - Physical therapy e.g., ice, heat or ultrasound
   - Physiotherapy e.g., massage and stretching
   - OTC-devices like orthosis, taping and heel pads
   - Prescribed orthosis
   - Shoe modification like higher heels
   - Cast/immobilization
   - Night splints

   Pharmacological treatments

   - External (topical) application of analgesics and/or anti-inflammatory gels
   - Therapy with prescription analgesic and/or NSAIDs
   - Local anesthetic injections
   - Local corticosteroid injections
6. Time gap of at least:
   - 6 weeks since the last cortisone injection;

- 4 weeks since the last iontophoresis, ultrasound and electromyostimulation;
- 1 week since the last NSAIDs and
- 2 days since the last analgesics, heat, ice, massage, stretching, night splinting and orthosis

7. VAS Scores of ≥ 5 on two VAS pain scales (heel pain when taking first steps of the day and heel pain while doing daily activities)
8. Willingness to refrain from the following painful heel related, concomitant therapies: iontophoresis; electromyostimulation; ultrasound; NSAIDs; steroid injections or surgery – Until Visit 7 of this study (shoe modifications and rescue pain medication are allowed during the entire study)
9. Willingness to keep a Subject Heel Pain Medication and Other Heel Pain Therapy Diary until 12 months after the last ESWT treatment
10. Females of childbearing potential may be entered if they provide a negative urine pregnancy test immediately before the first ESWT treatment
11. Willingness of females of childbearing potential to use contraceptive measures for 2 months after enrollment into the study

Exclusion Criteria

1. Subjects suffering from tendon rupture, neurological or vascular insufficiencies of the painful heel
2. Inflammation of the lower and upper ankle
3. History of rheumatic diseases, and /or collagenosis and/or metabolic disorders
4. Subjects with a history of hyperthyroidism
5. Malignant disease with or without metastases
6. Subjects suffering from Paget disease or calcaneal fat pad atrophy
7. Subjects suffering from Osteomyelitis (acute, subacute, chronic)
8. Subjects suffering from fracture of the Calcaneus
9. Subjects with an immunosuppressive therapy
10. Subjects with a long-term-treatment with corticosteroid
11. Subjects suffering form diabetes mellitus, severe cardiac or respiratory disease
12. Subjects suffering from coagulation disturbance and/or therapy with Phenprocoumon, Acetylsalicylicacid or Warfarin

13. Bilateral painful heel, if both feet need medical treatment
14. Subjects who, at entry, are known to have treatment planned within the next 8 weeks, which may abruptly alter the degree or nature of pain experiences such a that the shock wave therapy will no longer be necessary (e.g., surgery)
15. Time gap of less than:
    - 6 weeks since the last cortisone injection;
    - 4 weeks since the last iontophoresis, ultrasound and electromyostimulation;
    - 1 week since the last NSAIDs and
    - 2 days since the last analgesics, heat, ice, massage, stretching, night splinting and orthosis
16. Previous surgery of the painful heel syndrome
17. Previous unsuccessful treatment of the painful heel with a similar shock wave device
18. History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays
19. Subjects with significant abnormalities in hepatic function
20. Subjects in a poor physical condition
21. Pregnant female
22. Infection in the treatment area recently or in medical history
23. History or documented evidence of peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.
24. History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone nectosis, Reiter's syndrome, etc,
25. History or documented evidence of worker's compensation or litigation
26. Participation in an investigational device study within 30 days prior to selection, or current inclusion in any other clinical study or research project
27. Subjects who, in the opinion of the investigator, will be inappropriate for inclusion into this clinical study or will not comply with the requirements of the study

Clinical Study Procedures

Subjects who signed the study informed consent form and met the study eligibility criteria were randomized to receive either the active or placebo device treatment in a 1:1 allocation, but were not told of their randomization assignments. The

placebo handpiece and applicator were constructed so that the pressure impulses were blocked from being transferred to the treatment site, but otherwise were the same as the active handpiece and applicator in terms of sound, vibration and appearance.

After a screening visit to determine eligibility (Visit 1), the study started at Visit 2 with the first treatment (after randomization). The treatment protocol was the same for active and placebo subjects. The protocol specified up to 2500 impulses at each of three visits (Visits 2, 3 and 4), spaced 2 weeks apart. The first 500 impulses were applied at gradually increasing pressure (from 2 to 4 bar at 8 Hz) in order to desensitize the subjects to the pain of the impulses. After the 500 introductory impulses, 2000 treatment impulses were performed at a pressure of 4 bar. If the patient could not tolerate the pain during the first 250 introductory impulses, the investigator was allowed to administer a local anesthesia in these subjects using 5-10 ml of 0.5% bupivacaine in a medial injection or a local anesthetic spray.

The follow-up period began 1 week after the last treatment (Visit 5, 5 weeks after randomization). Follow-up evaluations were performed by study investigators who were not involved in the subject's treatment and were blinded as to the subject's randomization. Follow-up visits continued at 6 weeks (Visit 6), and 12 weeks (Visit 7) following the last treatment (or 10 weeks and 16 weeks following randomization, respectively).

Subjects considered to be "responders" to the EMS Swiss DolorClast® treatment were to continue to return for follow-up visits at 6 months (Visit 8), and 12 months (Visit 9) following the last treatment (7 months and 13 months following randomization, respectively). A "responder" was defined in the study protocol as a subject with at least 60 percent reduction in pain when taking first steps of the day and while doing daily activities or, if less than 60 percent reduction on the above, then the subject was satisfied with the outcome of the treatment, was able to work (if applicable) and did not require concomitant therapy to control heel pain. Data through Visit 7 is presented to support the PMA approval of the EMS Swiss DolorClast®.

Efficacy Endpoints

As a result of a blinded review of the study data, it was determined that a high correlation existed between the three heel pain measurements recorded using a visual analog scale (VAS): 1) heel pain upon taking first steps of the day; 2) heel pain while doing daily activities; and 3) heel pain after application of the

Dolormeter (a standardized pressure device) (r=0.85, r=0.79, and r=0.80, respectively). Therefore, a composite of these three measures was used as the primary efficacy endpoint, calculated two ways, first on a continuous scale as the sum score of the three measurements and second on a binary scale (success/failure) with "success" being defined as greater than 60 percent reduction in VAS score from baseline to Visit 7 (12 weeks after the last ESWT treatment) on at least two of the three heel pain measurements.

The secondary efficacy endpoints were the differences between groups at Visit 7 on the Roles and Maudsley Score, the SF-36 Quality of Life questionnaire, the investigator's global judgment of effectiveness of the treatment, and the subject's satisfaction with the outcome of the treatment.

Safety Endpoints

The safety of the EMS Swiss DolorClast® treatment was evaluated by comparing the type, device relationship, intensity and seriousness of adverse events reported by the subjects in both groups during treatment and during the study follow-up period.

Patient Accountability

All subjects who were enrolled in the study and received at least one treatment were evaluated for safety as the Safety Population (N = 251: 129 ESWT and 122 placebo). Subjects who received at least one treatment and had at least one follow-up evaluation were evaluated for efficacy as the Intent to Treat (ITT) population (N=243; 125 ESWT and 118 placebo). Efficacy was determined in the ITT patients who dropped out before completing all treatments or evaluations using the "Last Value Carried Forward" technique. Subjects who completed all three treatment sessions and all follow-up evaluations through Visit 7 (12 weeks after the last treatment) were considered the Per Protocol (PP) population (N=219: 111 ESWT and 108 placebo; for a total follow-up rate through Visit 7 of 87.3% (219/251)). Both ITT and PP populations were used in primary efficacy analysis. All missing values in both data analyses were handled using the "Last Value Carried Forward" (LVCF) technique.

The Safety Population included 152 subjects enrolled in five German centers (78 ESWT and 74 placebo) and 99 subjects enrolled in three United States centers (51 ESWT and 48 placebo).

Baseline Characteristics

The baseline characteristics and demographic data presented in Table 3 below for the ITT patient population demonstrate that the ESWT and placebo groups were comparable at baseline as all effect sizes using the Wilcoxon-Mann-Whitney test indicate equality and all p-values are not statistically significant ($p > 0.1$).

The ESWT and placebo groups were also very similar with respect to the prior failed therapies. All subjects met the study entry criteria of having tried and failed at least two pharmacological and two nonpharmacological therapies for their chronic proximal plantar fasciitis with the exception of one subject in the ESWT group and two subjects in the placebo group (ITT population).

Table 3: Baseline Characteristics, ITT Population (Intention-to-Treat)

Baseline Characteristics	ESWT ITT (N = 125)	Placebo ITT (N = 118)	Effect Size[1]
Age (years)			
Mean (SD)	52.4 (11.98)	52.0 (10.54)	0.5174
Range	23-77	18-78	
Sex Female	69.60% (87/125)	66.95% (79/118)	0.4867
Male	30.40% (38/125)	33.05% (39/118)	
Ethnic Origin			
White, Non-Hispanic	92.0% (115/125)	95.8% (113/118)	See footnote 2
Hispanic	4.0% (5/125)	0.8% (1/118)	
Afro-American	0.8% (1/125)	0	
Asian/Pacific Islander	2.4% (3/125)	2.5% (3/118)	
Other	0.8% (1/125)	0.8% (1/118)	
Body Weight (kg)			
Mean (SD)	79.0 (14.67)	81.1 (16.25)	0.4678
Range	48-118	50-131	
Height (cm)			
Mean (SD)	170.5 (10.06)	170.4 (8.36)	0.4945
Range	138-202	154-197	

Table 3: Baseline Characteristics, ITT Population (Intention-to-Treat) (Continued)

Baseline Characteristics	ESWT ITT (N = 125)	Placebo ITT (N = 118)	Effect Size[1]
Heel Pain Duration (months)			
Mean (SD)	25.6 (26.09)	24.9 (25.27)	0.5023
Range	6-99	6-99	
Heel pain (VAS) when taking first steps in the morning			
Mean (SD)	7.5 (1.49)	7.5 (1.57)	0.4941
Range	3-10	5-10	
Heel pain (VAS) while doing daily activities			
Mean (SD)	7.3 (1.48)	7.1 (1.53)	0.4525
Range	3-10	4-10	
Heel pain (VAS) after application of the Dolormeter			
Mean (SD)	7.2 (1.73)	7.1 (1.75)	0.4701
Range	0-10	2-10	
Roles and Maudsley score			
Mean (SD)	3.5 (0.52)	3.5 (0.57)	0.4917
Range	2-4	2-4	
SF-36 Physical Health Score			
Mean (SD)	45.0 (20.05)	46.7 (20.58)	0.5248
Range	5-88	9-86	
SF-36 Mental Health Score			
Mean (SD)	29.9 (20.07)	29.9 (19.38)	0.5055
Range	0-78	0-90	

[1]The Mann-Whitney estimator is the corresponding standardized effect size measure of the Wilcoxon-Mann-Whitney test. Benchmarks for group differences: 0.5 equality, 0.44/0.56 small, 0.36/0.64 medium, 0.29/0.71 large.

[2]Differences between groups not significant, p=0.4995 using the Fisher Exact Test (Mann-Whitney not appropriate for categorical variables).

Treatment Characteristics

The majority of subjects in the Safety Population completed all three treatment sessions 90.7% (117/129) ESWT and 95.9% (117/122) placebo. The average number of impulses delivered per treatment session ranged between 2413 and 2451 and was very similar between the two treatment groups (p-value>0.5 for all three treatments). Although 30 ESWT and five placebo subjects complained of pain during treatment, only one subject requested local anesthesia for the pain. Only one device malfunction was reported during the study (placebo applicator did not function and treatment was conducted with a second applicator). No subject in either group experienced an adverse event as a result of a device malfunction.

Primary Efficacy Results

The time point for evaluating the primary efficacy of the treatments was at Visit 7 (12 weeks following the third treatment session). Results are presented for both the ITT population (subjects who completed at least one treatment session and one evaluation session) and the Per Protocol population (subjects who completed all three treatment sessions and all follow-up evaluations). Missing data was handled using the Last Value Carried Forward (LVCF) approach. Pain scores were adjusted for subjects who took interfering analgesics or had other therapies for their chronic proximal plantar fasciitis within predefined timeframes prior to evaluation visits by adding 2 points to their VAS scores for the affected visit. EMS conducted supportive sensitivity analyses to confirm the results obtained using these methods.

Table 4 presents the primary efficacy results for the ITT population. In the ESWT group, the mean composite pain score (sum of VAS scores for the three pain measures) decreased from 22.0 ± 3.24 at baseline to 9.7 ± 8.56 at Visit 7, for a mean percent decrease (i.e., improvement) of 56 percent. In the placebo group, the mean composite pain score decreased from 21.6 ± 3.22 at baseline to 12.3 ± 9.39 at Visit 7, for a mean percent decrease of 44 percent. These results show a significant improvement in the mean composite VAS score for the ESWT group as compared to the placebo group (p=0.022).

The result for overall success rate, defined as greater than 60 percent reduction in VAS pain scores on at least two of the three pain measures, was also superior for the ESWT group as compared to the placebo group. Sixty-one percent (75/123) of the ESWT subjects met this success criterion as compared to 42 percent (49/116) of the placebo subjects group (p=0.002).

Table 4: Primary Efficacy Results for ITT Population at Visit 7 - Composite Scores for Three VAS Measures

	ESWT (N_{itt}=125)	Placebo (N_{itt}=118)	Effect Size[1]	P-Value One Sided
Composite VAS Score: Percent Change from Baseline at Visit 7			0.5753	0.0220[2]
Mean (SD)	-56.0 (39.31)	-44.1 (41.81)		
Median	-72.1	-44.7		
Overall Success Rate (>60% reduction in VAS on at least two pain measures)	60.98% (75/123)	42.24% (49/116)	0.5937	0.0020[3]

[1]Mann-Whitney (MW) effect size
[2]Wilcoxon-Mann-Whitney test
[3]Unconditional Exact Röhmel-Mansman test

Table 5 presents the results for the Per Protocol population. In this population, where all subjects received the full prescribed three treatments, the results for the ESWT group improved (as compared to the ITT population) while the results for the placebo group stayed essentially the same (as compared to the ITT population). The superiority of the Per Protocol ESWT group as compared to the Per Protocol placebo group is confirmed by this analysis ($p<0.01$ on both composite VAS score and overall success).

Table 5: Primary Efficacy Results for Per Protocol Population at Visit 7 - Composite Scores for Three VAS Measures

	ESWT (N_{pp}=111)	Placebo (N_{pp}=108)	Effect Size[1]	P-Value One sided
Composite VAS Score: Percent Change from Baseline at Visit 7				
Mean (SD)	-60.6 (35.97)	-44.2 (42.11)	0.6037	0.0041[2]
Median	-75.0	-44.3		
Overall Success Rate (>60% reduction in VAS on at least two pain measures)	64.55% (71/110)	43.40% (46/106)	0.5788	0.0011[3]

[1]Mann-Whitney (MW) effect size
[2]Wilcoxon-Mann-Whitney test
[3]Unconditional Exact Röhmel-Mansman test

Secondary Efficacy Results

Table 6 presents the results of the secondary efficacy criteria, including the Roles and Maudsley Score, SF-36 Quality of Life evaluation, investigator's global judgment of effectiveness, and subject's satisfaction with their therapy outcome. The ESWT group demonstrated greater improvements from baseline to Visit 7 on all secondary measures as compared to the placebo group ($P < 0.025$ one-sided).

Table 6: Secondary Efficacy Results for ITT Population

	ESWT (N_{itt}=125)	Placebo (n_{itt}=118)	Effect Size[2]	P-Value One Sided
Roles and Maudsley Score				
Excellent or Good	58.40% (73/125)	41.52% (49/118)	0.5973	0.0031[3]
Fair or Poor	41.60% (52/125)	58.48% (69/118)		
SF-36 Physical[1] Percent Change from Baseline at Visit 7				
Mean / SD	-37.2 (48.42)	-19.5 (52.13)	0.6191	0.0013[3]
Median	-44.1	-23.9		
SF-36 Mental[1] Percent Change from Baseline at Visit 7				
Mean / SD	-14.6 (62.89)	+8.4 (99.06)	0.5850	0.0163[3]
Median	-22.8	-14.3		
Investigator Judgment of Effectiveness				
Very good or Good	70.80% (80/113)	40.91% (45/110)		
Moderate	10.62% (12/113)	20.91% (23/110)	0.6335	0.0002[3]
Unsatisfactory or Poor	18.58% (21/113)	38.18% (42/110)		
Patient Judgment of Therapy Satisfaction				
Very or Moderately Satisfied	63.16% (72/114)	46.36% (51/110)		
Slightly Satisfied or Neutral	18.42% (21/114)	10.00% (11/110)	0.5984	0.0045[3]
Dissatisfied	18.42% (21/114)	43.64% (48/110)		

[1]SF-36 scores standardized using a scale from 0 (best score) to 100 (worst score); negative percent change from baseline indicates improvement.
[2]Mann-Whitney (MW) effect size
[3]p-values of one-sided test for superiority using the Wilcoxon-Mann-Whitney test

Safety Results

Adverse events are presented in section VIII above.

Follow-up Results at 6-Months and 12-Months

Treatment Responders at Visit 7 continued in the study and returned for two additional follow-up visits, Visit 8 at 6 months following the last treatment and Visit 9 at 12 months following the last treatment.

Results at both the 6-month and 12-month follow-up visits were similar to the results presented in Table 4 for visit 7. Results at the 12-month follow-up (Visit 9) are shown in Table 7 for the ITT population. Results include the composite scores and overall success rate in accordance with the same criteria used for the primary efficacy results at Visit 7 (Table 4). Missing data was handled using the Last Value Carried Forward (LVCF) approach. Pain scores were adjusted for subjects who took interfering analgesics or had other therapies for chronic proximal plantar fasciitis within predefined timeframes prior to evaluation visits by adding 2 points to their VAS scores for the affected visit.

In both the ESWT group and the placebo group, the mean composite scores increased slightly from the scores at Visit 7. The results continue to show an improvement in the mean composite VAS score for the ESWT group as compared to the placebo group. Likewise, the overall success rate (defined as greater than 60 percent reduction in VAS pain scores on at least two of the three pain measures) for the ESWT group continued to be superior to that of the placebo group. These results confirm that the results obtained at the 3-month primary efficacy endpoint are maintained over a period of up to 12 months.

Table 7: Efficacy Results for ITT Population at Visit 9 (12-months) - Composite Scores for Three VAS Measures

	ESWT (N_{itt}=125)	Placebo (N_{itt}=118)
Composite VAS Score: Percent Change from Baseline at Visit 9		
Mean (SD)	-61.9(43.62)	-46.5 (45.52)
Median	-84.8	-43.2
Overall Success Rate (>60% reduction in VAS on at least two pain measures)	63.41% (78/123)	43.97% (51/116)

XI Conclusions Drawn from the Study

The preclinical and clinical data presented in this Summary of Safety and Effectiveness provides reasonable assurance that the EMS Swiss DolorClast® is safe and effective when used in accordance with the device labeling. The results of a multicenter, randomized, placebo-controlled, double-blinded clinical study demonstrate that treatment of chronic proximal plantar fasciitis with the EMS Swiss DolorClast® provides relief from chronic proximal plantar fasciitis for up to 12 weeks duration in patients who have previously failed conservative treatment. The most likely side effect is pain during treatment, which was reported by 23 percent of ESWT treated subjects in the clinical study.

XII Panel Recommendation

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA application was not referred to the General Surgical Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII CDRH Decision

FDA issued an approval order on May 8, 2007.

The applicant's manufacturing facility was inspected and was found to be in compliance with the Quality Systems Regulation (21 CFR 820).

XIV Approval Specifications

Directions for Use: See the Device Labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Post Approval Requirements and Restrictions: See Approval Order.