1. Summary of Safety and Effectiveness

A. General Information

Device Generic Name:	Extracorporeal Shock Wave Therapy (ESWT) system
Device Trade Name:	SONOCUR® Basic
Applicant Name and Address:	Siemens Medical Solutions USA, Inc. Sales and Service Group 186 Wood Avenue South Iselin, NJ 08830
Application Number:	P010039
Date of Panel Recommendation:	None

Date of Notice of Approval to Applicant: July 19, 2002

B. Indications for Use

The Siemens SONOCUR Basic is a non-surgical alternative for the treatment of chronic lateral epicondylitis (commonly referred to as tennis elbow) for patients with symptoms of chronic lateral epicondylitis for 6 months or more and a history of unsuccessful conservative treatments.

C. Contraindications

There are no known contraindications to ESWT with the SONOCUR Basic for treatment of chronic lateral epicondylitis.

D. Warnings

The following warnings pertain to the use of the SONOCUR Basic for treatment of chronic lateral epicondylitis (tennis elbow).

- Operators of the *SONOCUR Basic* should be aware of the proper use of the device in delivering the correct number of shocks and in localizing the proper area to be treated.

- ESWT with the SONOCUR Basic should be prescribed by and performed under the supervision of a physician trained and experienced in the care of patients with lateral epicondylitis.
- If the patient moves after correct positioning, re-perform localization if necessary. Failure to maintain correct positioning could result in misdirection of the shockwave and injury to adjacent nerves or blood vessels.
- If patients experience severe pain/discomfort at the application site during treatment, the system operator should decrease the penetration depth of the therapeutic shock wave focus by increasing the water level in the coupling bellows.
- If patients experience a vaso-vagal reaction during treatment, the patient should be reclined to a supine position until symptoms disappear.
- Patients currently undergoing systemic anticoagulation therapy (example—coumadin, heparin) should consult their physicians regarding temporary discontinuation of such medications before ESWT to prevent potential ecchymosis/bruising.
- Patients on daily aspirin therapy should temporarily discontinue aspirin intake 1 week before ESWT therapy.

E. Precautions

The following are precautions for the SONOCUR Basic system for treatment of chronic lateral epicondylitis (tennis elbow):

- Electromagnetic compatibility (EMC):

  If electromagnetic interference between the extracorporeal shock wave system and nearby electronic equipment is suspected (as evidenced by erratic behavior with either device), it is recommended that their distance be increased until proper operation resumes. If it is necessary to operate an electronic device in close proximity to the ESWT system during treatment, the device and the ESWT system should be tested for proper simultaneous operation prior to clinical use.
- Never remove any of the cabinet covers to the system's electronics. The high voltage power supply circuits utilized by extracorporeal shock wave systems use voltages that are capable of causing serious injury or death from electric shock.
- If the device malfunctions during treatment or the treatment is discontinued, the therapeutic effects may not be as noticeable.

The safety and effectiveness of the SONOCUR Basic has not been established for:

- Pregnant women
- Patients younger than 18 years of age.
- Patients with a coagulation abnormality, thrombopathy, infection, tumor, cervical compression syndrome, cervical or upper extremity arthritis, local arthrosis, neurologic abnormality, or radial nerve entrapment
- Patients who have had previous surgery for lateral epicondylitis
- Patients who suffer from severe systemic diseases that may lead to sensory changes or neuropathic pain. For example, this may include diseases such as gout, diabetes mellitus, rheumatoid arthritis.
- Patients with cardiac pacemaker
- Patients who received physical or occupational therapy less than four (4) weeks prior to ESWT
- Patients who received a local steroid injection less than six (6) weeks prior to ESWT
- Patients with tennis elbow affecting both arms or who have had previous surgery for this condition

F. Device Description

Overview

The design of the SONOCUR Basic is based on Siemens extracorporeal shock wave lithotripsy (ESWL) devices. A shock wave is generated at the base of the shock head by an electromagnetic acoustic source (EMAS) within the shock head. When a high voltage pulse from a capacitor discharge is transmitted via the slab coil, a current is induced in the aluminum-foil membrane. The membrane is then rapidly repelled, which causes a shock wave. This shock wave travels through the water filled shock head to the focusing lens. This acoustic lens focuses the energy of the propagated pressure wave to a small concentrated point some known distance from the lens. The shock wave passes through the lens and into a water-filled coupling head (bellows).

By palpation, the treatment area (lateral epicondyle) is located. The shock head is positioned using the articulating device arm, aligned with the treatment area, and coupled to the patient's skin using ultrasonic gel. The release of shock waves is controlled by the user via the system control console, which is menu-driven. The repetition frequency of shock wave release ranges from 1Hz to 4Hz, and is adjusted by the user at the control console. Shock wave pulses are released either by manually pressing the release button on the handswitch or by holding down the release button for a preset number of pulses.

Component List

The SONOCUR Basic device consists of the following components in a transportable unit:

A. Electromagnetic acoustic source (EMAS) with coupling bellows and keys for the shock wave release, the brakes and controlling the pump
B. Trolley with high tension capacitor charging unit and water conditioning system
C. Control console with controls for system parameter setting such as energy and pulse frequency
D. Articulating arm to position the EMAS (or shock head)

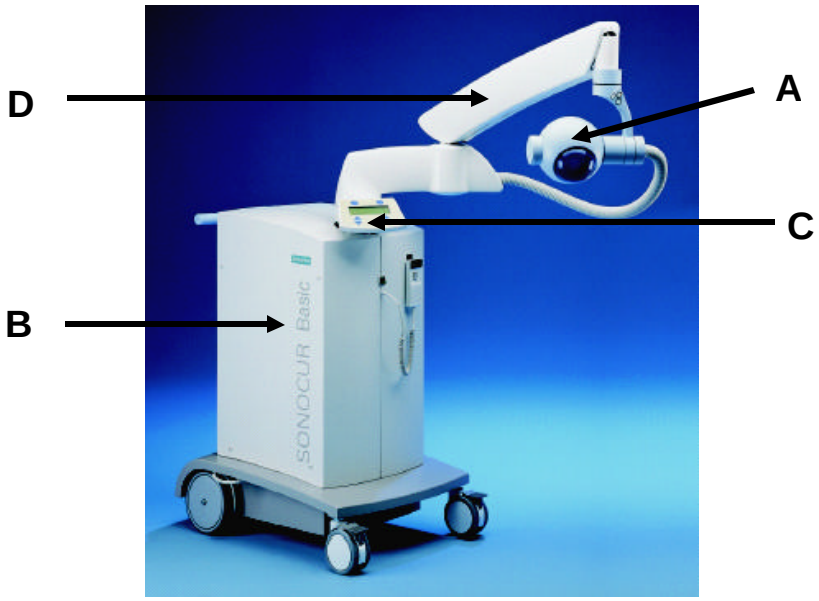

Figure 1: SONOCUR Basic Components

Electromagnetic acoustic source (EMAS)

The electromagnetic acoustic source (EMAS) is mounted at the base of the shock head. The shock head housing connects the polystyrene acoustic lens with the EMAS. The lens end of the head is fitted with a water-filled silicon coupling bellows.

The spaces between the EMAS and the lens and between the lens and the coupling bellows (or between the EMAS and the coupling head for the elliptical-spherical lens shock head) are filled with water.

The coupling head provides an acoustically favorable path for the focused pressure wave as it moves from the shock head to the patient. A water reservoir, pump, and valve system are used to adjust penetration depth to individual patients anatomy

When the pressure pulse capacitor charging unit discharges, it sends a short current pulse through the slab coil of the EMAS. By the law of induction, the

increasing current in the slab coil induces a magnetic field around the coil. Similarly, as this magnetic field builds, it induces eddy currents in the metal diaphragm (made of an aluminum-alloy disk), which, in turn, induces a magnetic field near the metal diaphragm.

The magnetic field that is induced in the diaphragm has the opposite polarity of the field set up near the slab coil. Since these magnetic fields have opposite polarities, they repel each other and the diaphragm is forced away from the rigidly fixed slab coil. The resulting motion of the diaphragm creates a compression wave, which travels through the water within the shock head.

A polystyrene acoustic lens is mounted in the shock head above the diaphragm. This lens focuses the compression wave to a small focal region.

Pressure Pulse Capacitor Charging Unit

The large current impulse used to create the compression wave in the pressure pulse generator is a result of a capacitive discharge through the EMAS. Initiating the capacitive discharge is accomplished with a spark gap, which consists of two electrodes in a cavity. This potential difference across the capacitor can be varied for the EMAS and ultimately determines the pressure of the wave created by the EMAS and the pressure pulse which forms in the focal region.

Water systems

The water conditioning system, which has a compact design, fits with all its components in the housing of the transportable trolley. The water conditioning system is composed of two independent water circuits:

- cooling system and
- coupling system (the area between the lens and coupling bellows).

Control Console

The system parameters can be controlled and displayed on the control console. In the main menu, the following parameters can be selected and/or displayed

- number of pulses per treatment
- number of pulses currently applied during session
- energy level indication
- warning and error messages

Articulating arm to position the shock head

The shock head is mounted on a unique articulating arm. This arm can be flexibly moved in three planes after releasing the electromagnetic brakes. The pain is identified by palpation by the physician or by subjective assessment of the patient. The shock head is coupled to the patient's skin, using ultrasonic gel. After applying a sufficient amount of ultrasound gel to the patient's skin and to the coupling bellows, the shock head and pressure pulse focus are positioned to the location of the pain and the brakes are locked.

The penetration depth of the therapeutic pressure pulse focus in the patient body can be set by varying the water level in the bellows. To decrease or increase the penetration depth, water is pumped into or out of the bellows.

G. Adverse Effects of the Device on Health

Adverse events observed during a clinical study of 114 patients that were associated with extracorporeal shock wave therapy (ESWT) include those listed below, categorized by frequency:

Adverse events reported in >20% of patients:

- pain at, or surrounding the treatment site

Adverse events reported in <20% of patients

- nausea
- myalgia
- joint disorder
- pallor
- dizziness
- hypertonia
- hypesthesia
- paresthesia
- tremor
- vasodilation
- application site reaction
- sweating

The number and frequency of each reported event is summarized in Table 1 below:

Table 1: Device Related Adverse Events at 12 Week Follow-up

	Active			Placebo		
	Number of Patients [1]	Number of Occurrences	% of Patients [2]	Number of Patients [1]	Number of Occurrences	% of Patients [2]
Pain	28	60	50%	13	32	22.4
Nausea	10	10	17.9%	0	0	0%
Application Site Reaction	6	8	10.7%	5	5	8.6%
Sweating	5	5	8.9%	0	0	0%
Dizziness	4	4	7.1%	0	0	0%
Hypertonia	3	5	5.4%	3	3	5.2%
Hypesthesia	3	5	5.4%	1	2	1.7%
Paresthesia	3	4	5.4%	8	12	13.8%
Joint Stiffness	2	2	3.6%	0	0	0%
Myalgia	2	2	3.6%	0	0	0%
Tremor	2	2	3.6%	0	0	0%
Vasodilation	2	2	3.6%	0	0	0%
Pallor	1	1	1.8%	0	0	0%
Accidental Injury	0	0	0%	2	3	3.4%
Headache	0	0	0%	2	7	3.4%
Peripheral Edema	0	0	0%	1	1	1.7%

Twitching	0	0	0%	1	1	1.7%
Sinusitis	0	0	0%	1	2	1.7%

1. Number of patients experiencing at least one adverse event
2. Based on the total number of patients in each treatment group: active treatment group=56 patients, placebo group=58 patients

During the study, three patients exhibited benign, non-life threatening EKG changes that were determined by the investigators and cardiologists not to be treatment related.

Other potential adverse events not seen during the clinical study include:

- Neuropathy
- Tendon rupture
- Local hematoma
- Misdirection of energy

H. Alternate Practices and Procedures

Alternative therapies can be divided into nonsurgical and surgical treatment. Among the most common initial treatments are rest and application of cold to the symptomatic region. The use of aspirin very often is a first choice. Nonsteroidal anti-inflammatory medications including indomethacin seem to be helpful in some patients. The physical therapy modality of high-voltage electric stimulation has been helpful in relieving pain and inflammation. If the process does not respond to the above treatment choices, a cortisone injection may be appropriate. Various surgical treatments can also be considered as an alternative to ESWT.

I. Marketing History

In October 1996, SONOCUR Basic was made commercially available in the European Market. Since then, it has been available in countries other than the United States, Japan and Taiwan. SONOCUR Basic has never been withdrawn from marketing for any reason related to safety or effectiveness of the device.

J. Summary of Preclinical Testing

Shock wave characterization

Shock wave output from the SONOCUR Basic was characterized according to the draft FDA guidance, “Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements”. The following figure (figure 2) shows the peak positive pressure at the focus as a function of Energy Level (system output range):

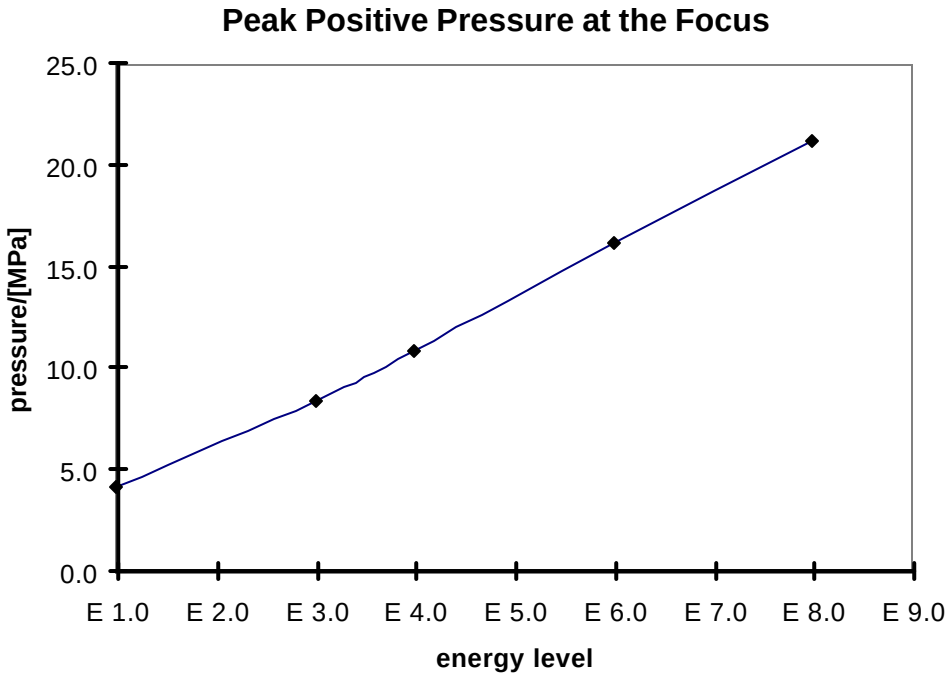

Figure 2. Peak Positive Pressure versus Energy Level

Energy Flux Density Output versus SONOCUR Basic Energy setting

Energy setting	1	2	3	4	5	6	7	8
Energy Flux Density in mJ/mm^2	0.03	0.06	0.12	0.17	0.25	0.32	0.41	0.50

All values based on measurements with PVDF membrane hydrophone.
Manufacturer: GEC-Marconi Research Center
Type: Y-33-7603

Biocompatibility

The material of the coupling bellows which contacts the patient conforms to the international standard ISO-10993 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". Sensitivity and irritation testing, USP biological testing (classification VI), intracutaneous toxicity, and implantation testing were performed. The ISO-10993 testing showed that there were no reactions identified as sensitization and no irritant/corrosive effects.

Noise level testing

The amplitude of the noise generated by the shock head of the SONOCUR Basic system was measured with a Larson Davis sound meter. The equipment conforms to Class I requirements according to IEC 804. The sound measurements were performed at a distance of 1m from the SONOCUR Basic unit with the following parameters: energy levels 1 – 8, minimal (1 Hz) and maximum (4 Hz) repetition frequency, and with and without patient simulation. The surface sound pressure levels measured are below the Occupational Safety and Health Administration (OSHA) standard for all exposure times (from 0.5 hours/day to 8 hours/day).

Animal testing

Animal studies were conducted using an early prototype of the Sonocur Basic system, which used the same mechanism of electromagnetic shock-wave generation, by Rompe et. al [Dose related effects of shock waves on rabbit tendon Achillis: A Sonographic and Histological Study. Journal of Bone and Joint Surgery (Br) 1998.80-B:546-52]. For this study, forty-two (42) New Zealand rabbits (84 total tendons) were randomized into four treatment groups:

1) Group A: 1000 shock-wave impulses of an energy flux of 0.08mJ/mm^2
2) Group B: 1000 shock-wave impulses of an energy flux of 0.28mJ/mm^2
3) Group C: 1000 shock-wave impulses of an energy flux of 0.60mJ/mm^2
4) Group D: no shock-wave therapy (control group)

During the study, sonographic and histological tests were performed and the results showed no changes in Group A, transient swelling of the tendon in Group B. With Group C (energy flux of 0.60mJ/mm^2), there was the formation of paratendinous fluid with a significant increase in the anteroposterior diameter of the tendon. In addition, there was marked histological changes with increased eosin staining, fibrinoid necrosis, fibrosis in the paratenon and infiltration of inflammatory cells. It was concluded that energy flux densities greater than 0.28mJ/mm^2 should not be used clinically to treat tendon disorders. The Sonocur Basic system uses 0.08mJ/mm^2 for the treatment of lateral epicondylitis.

K. Summary of Clinical Studies

As a first step in its clinical development for the U.S. market, Siemens sponsored a small randomized, double-blinded, placebo-controlled pilot study to assess the feasibility of using the Sonocur Basic system in the treatment of lateral epicondylitis. An analysis of the three-month study data showed that the ESWT system is safe, with the most frequently reported adverse event being pain during treatment. The results also showed an efficacy advantage for the active treatment group in reducing pain at 12 weeks post-treatment compared with baseline, even though there was a higher than expected “placebo effect” that was consistently observed over the entire three month follow-up period. To reduce this placebo effect and increase the active treatment effect, certain adjustments to the study design were made (including the inclusion/exclusion criteria and treatment

application) and Siemens continued further clinical testing of the Sonocur Basic ESWT system. This additional testing was conducted as a multi-center clinical trial, which is described below in further detail.

Study Design and Objectives

The Siemens Sonocur Basic multi-center pivotal trial was a randomized, double-blind (patients and evaluators), placebo-controlled, parallel treatment study. A total of 114 patients were enrolled in the study at 3 investigational sites.

Patients with chronic tennis elbow were examined and randomized to one of two treatment groups (active, placebo). Each patient was scheduled to receive three treatments: once a week for a three-week period. For all completed treatments, a maximum of 2100 impulses per treatment session was delivered for a total energy delivery of 9.27J for all three sessions. The procedure for the active and placebo treatments was performed identically except that for patients receiving the placebo treatment, a sound-reflecting pad was placed between the treatment site and the shock wave head. No local anesthetic injection or analgesic was allowed during treatment.

During the study, assessments of pain level and functional activity were performed. At each visit, the pain intensity was evaluated using the Thomsen provocation test (resisted wrist extension). The patient was asked to record the level of pain that he/she was experiencing on a visual analog scale (VAS), which was a 100mm scale with 0 for no pain and 100 for intolerable pain. In addition, functional improvement was also examined using an **U**pper **E**xtremity **F**unctional **S**cale, or UEFS, test. For this test, patients in the study were asked to score their ability to perform specific daily chores (such as opening jars/doors, washing dishes) on a scale from 1 to 10, with a score of 1 meaning that the patient had no problem at all and a score of 10 meaning that the patient could not perform the activity. Additional measures of efficacy were examined including the patient's overall impression, grip strength, activity evaluation (ability to perform activities that were limited by his/her tennis elbow condition), and pain medication consumption. Safety assessments included an assessment of adverse events, physical examination, X-rays, vital signs, 12-lead EKG, clinical labs, and proportion of patients who couldn't tolerate treatment.

Patients were scheduled for follow-up evaluations, occurring at 1-, 4-, 8-, 12-weeks, 6-months, and 12-months post-treatment. The primary analysis of the safety and efficacy data was performed after all patients were enrolled, treated, and completed their 12-week follow-up requirements.

Primary and Secondary Efficacy Endpoints:

- ♦ *The primary efficacy endpoint* was at least a 50% reduction from baseline to Week 12 post-treatment in the pain visual analog scale (VAS) during resisted wrist extension

- ♦ *The secondary efficacy endpoint* was an improvement from baseline to Week 12 post-treatment in the patient's mean upper extremity function score. Function was assessed using the Upper Extremity Function Scale (UEFS) (Pransky et al.).

Subject Inclusion and Exclusion

The *inclusion criteria* included:

- history of lateral epicondylitis for at least 6-months;
- pain that is unresponsive to two of three conventional therapy programs (local steroid injections, physical/occupational therapy, non-steroidal anti-inflammatories);
- pain by palpation of the lateral epicondyle;
- baseline pain that was = 40 during resisted wrist extension ("Thomsen provocation test") on a 100mm visual analog scale (VAS); and

The *exclusion criteria* included:

- < 18 years of age;
- received local steroid injections within 6 weeks, physical/ occupational therapies within 4 weeks, or non-steroidal anti-inflammatories within 1 week prior to randomization;
- received systemic therapeutic anticoagulants;
- active bilateral epicondylitis;
- history *and/or* physical findings of cervical compression syndrome, cervical or upper extremity arthritis, local arthrosis or neurologic abnormality, rheumatoid disease, or radial nerve entrapment;
- previous surgery for lateral epicondylitis;
- participated in a Workman's Compensation Program or planned to apply for the Program;
- thrombopathy, infection, tumor, or other severe systemic diseases;
- arthrosis of the elbow, as confirmed by X-ray diagnosis (AP, lateral views);
- pregnancy;
- participated in a study with any experimental therapy within the last 30 days.

Study Population

Of the 114 patients enrolled in the study and included in the intent-to-treat (ITT) cohort, 56 patients were assigned to the active treatment group and 58 patients were assigned to the placebo group. Two (3.6%) active treatment group patients could not tolerate treatment and discontinued from the study prior to completing all three scheduled treatments. A third active treatment group patient was discontinued due to a low platelet count, which was found to be a pre-existing condition prior to study participation. Of the 58 placebo patients, 3 (5.2%) patients discontinued prior to the 12- week follow-up period to seek alternative therapy.

Patient demographics and treatment history are summarized in Table 2, below. The mean age for the active treatment group was 47 years (ranging from 35-71 years), and the mean age for the placebo group was 47 years (ranging from 35-60 years). There were 27 male (48.2%) and 29 female (51.8%) patients in the active treatment group and 27 male (46.6%) and 31 female (53.4%) patients in the placebo group. The mean height was 171 cm and the mean weight was 76kg. Physical exam and medical histories at baseline were also similar between the treatment groups.

Table 2: Patient Demographics and Treatment History

Characteristic	Active Treatment Patients (N=56)	Placebo Treatment Patients (N=58)
Age (years)		
Mean	47	47.3
Range	35-71	35-60
Gender		
Male	27 (48.2%)	27 (46.6%)
Female	29 (51.8%)	31 (53.4%)
Height (cm)		
Mean	170.9	171.8
Range	152.4-188.0	149.9-190.5
Weight (kg)		
Mean	75.9	78.9
Range	50.9-120.0	53.0-120.2
Affected Arm		
Right	35 (62.5%)	41 (70.7%)
Left	21 (37.5%)	17 (29.3 %)
Prior Therapies*		
All three	41 (73.2%)	43 (74.1%)
Steroid Injections & PT/OT	4 (7.1%)	6 (10.3%)
Steroid Injections & NSAIDs	6 (10.7%)	5 (8.6%)
PT/OT & NSAIDs	5 (8.9%)	4 (6.9%)
Symptom Duration (months)**		
Mean	21.3	20.8
Range	6.0-178.0	6.0-176.0

* PT/OT= physical and occupational therapy, NSAIDs= non-steroidal anti-inflammatories

** from date of initial diagnosis by a physician to enrollment into the study

Each treatment group (active, placebo) had lateral epicondylitis for an average of 21 months (12-month median) prior to randomization. In total, seventy-six (66.7%) patients had their right arm affected and 38 (33.3%) patients had their left arm affected. More than 70% of the patients in each treatment group had all three types of therapies (injections, PT/OT, NSAIDs) prior to enrollment, and 54 (93.1%) placebo patients and 51 (91.1%) active treatment patients had steroid injections.

Treatment Characteristics:

All patients were scheduled to receive three treatments: once a week for a three week period. For all completed treatments, a maximum of 2100 impulses per treatment session was delivered for a total energy delivery of 9.27J for all three sessions. The procedure for the active and placebo treatments was performed identically except that for patients receiving the placebo treatment, a sound reflecting pad was placed between the treatment site and the shock wave head. No local anesthetics were used for treatment application.

During the study, the majority of patients (96.5%) completed all three treatments without any treatment interruptions or abortions. As summarized in Table 3, below, two active treatment patients had treatments aborted due to adverse patient reactions (elbow pain, nausea, diaphoresis, light headedness) and two patients (1 active, 1 placebo) had treatments interrupted due to temporary device malfunctions.

Table 3: Number of patients with treatments interrupted or aborted

		Active (n=56)	Placebo (n=58)
Patients with Treatments Interrupted	Adverse Event	0	0
	Machine Malfunction	1 (1.8%)	1 (1.7%)
Patients with Treatments Discontinued	Adverse Event	2 (3.6%)	0
	Machine Malfunction	0	0

Overall, the systems performed reliably over the course of the study with few reported problems. For two of the three systems used in the clinical trials, device malfunctions were reported. One device malfunction was due to a broken system cable that prevented shock wave delivery, and one reported malfunction was due to a defective shock wave module that needed to be replaced (with the water cooling system cleaned and serviced). Given their low frequency of occurrence, its unlikely that these system malfunctions significantly affected the overall study results.

Efficacy and Safety Results

Efficacy Results:

For the ITT population (refer to Table 4, below), the placebo and active treatment groups had comparable pain scores at the baseline evaluation. The average pain score for patients who received the active treatment was 74 at baseline and 37.6 at 12 weeks. The average score for the placebo patients was 75.6 at baseline and 51.3 at 12 weeks.

Table 4: Summary of Patient Pain Assessments from Baseline to Week 12

Treatment Group		Baseline	Week 1	Week 4	Week 8	Week 12
Active	**N**	56	56	56	56	56
	Mean	73.98	55.55	49.09	40.77	37.59
	SD	15.79	25.18	26.79	28.67	28.68
Placebo	**N**	58	58	58	58	58
	Mean	75.57	63.97	60.57	54.81	51.33
	SD	16.00	23.19	25.48	25.12	29.65

N=number of patients
SD= standard deviation

The primary efficacy endpoint was at least a 50% reduction from baseline to 12-weeks post-treatment in the pain visual analog scale (VAS) during resisted wrist extension. For the intent-to-treat cohort, the results show that the active treatment group had 34/56 (60.7%) of the patients and the placebo group had 17/58 (29.3%) of the patients achieving at least a 50% reduction in pain during provocation at Week 12 compared with baseline. There was a statistically significant (p=0.001) between group difference.

The secondary efficacy endpoint was an improvement from baseline to Week 12 post-treatment in the patient's mean upper extremity function scale (UEFS) score. For the ITT population (refer to Table 5, below), the placebo and active treatment groups had comparable mean upper extremity function scores (UEFS) at the baseline evaluation. The mean UEFS score for the active treatment group was 4.68 at baseline (SD=1.78) and the mean UEFS score for the placebo group was 4.63 (SD=1.8) at baseline. At Week 12, there was a statistically significant (p=0.01) difference between groups in the mean UEFS scores, compared with baseline.

Table 5: Summary of UEFS Assessments from Baseline to Week 12

Treatment Group		Baseline	Week 1	Week 4	Week 8	Week 12
Active	**N**	56	53	51	52	53
	Mean	4.68	3.23	2.80	2.54	2.25
	SD	1.78	1.89	1.70	1.52	1.57
Placebo	**N**	58	57	57	55	54
	Mean	4.63	3.71	3.79	3.54	3.23
	SD	1.80	1.77	1.98	2.12	2.09

N=number of patients, SD=standard deviation

The percent improvement in the average efficacy scores (pain, UEFS, patient's overall impression, activity level, and grip strength testing) at 12-weeks compared with baseline is summarized in Table 6, below.

Table 6: Percent Improvement in Average Efficacy Scores at 12 Weeks, Compared with Baseline

	SONOCUR Basic ESWT			Placebo (Mock)		
	average score at beginning of study	average score at 12 weeks	% improvement	average score at beginning of study	average score at 12 weeks	% improvement
Pain *	74	37.6	49%	75.6	51.3	32%
UEFS *	4.7	2.3	**51%**	4.6	3.2	**30%**
Activity Evaluation *	7.7	3.5	**55%**	7.4	5	**32%**
Overall Impression *	70.3	32.8	**53%**	66	46.2	**30%**
Grip Strength Testing	71	87.1	**23%**	72.5	81.5	**12%**

* statistically significant ($p<0.05$) between group difference. p-value is calculated using one way ANOVA

Safety Results:

In general, the nature, severity, frequency, duration and resolution of adverse events were similar in the active and placebo group, with the exception of certain vasovagal responses (i.e. nausea, sweating, dizziness, hypesthesia) and reports of pain during treatment for the active group.

Table 1 (page 6: Adverse Device Effects of the Device on Health) summarizes the type and frequency of adverse events that were categorized as being possibly or probably related to the study treatment.

The following table (Table 7) shows the occurrence of adverse events for the active treatment group that were judged to be possibly or probably treatment related over the course of the 12-month study period.

Table 7. Active Treatment Group: Adverse Events Through 12 Months of Follow-up

Adverse Events	Treatment Period				Follow-up Period [1]					
	Day of Treatment (*Treatments 1, 2, 3*) [N=56]		Between Treatments 1-2 [N=56]	Between Treatments 2-3 [N=54]	<=1 Week [N=53]	>1-4 Weeks [N=51]	>4-8 Weeks [N=52]	>8-12 Weeks [N=53]	>12 Weeks-6 Months [N=48]	>6-12 Months [N=46]
	# of patients [2]	# of occurrences	# of patients [2]	# of patients [2]	# of patients [2]	# of patients [2]	# of patients [2]	# of patients [2]	# of patients [2]	# of patients [2]
Pain	24	46	6	5	4	5	3	1	0	0
Nausea	10	10	0	0	0	0	0	0	0	0
Application Site Reaction	4	6	2	2	3	2	2	1	1	*
Sweating	5	5	0	0	0	0	0	0	0	0
Dizziness	4	4	0	0	0	0	0	0	0	0
Hypertonia	2	3	1	0	2	1	1	1	0	0
Hypesthesia	3	5	0	0	0	0	0	0	0	0
Paresthesia	3	4	0	0	0	0	0	0	0	0
Joint Stiffness	1	1	1	2	1	1	1	1	1	*
Myalgia	1	1	1	0	0	0	0	0	0	0
Tremor	2	2	0	0	0	0	0	0	0	0
Vasodilation	2	2	0	0	0	0	0	0	0	0
Pallor	1	1	0	0	0	0	0	0	0	0

[1] relative to the last treatment, using protocol defined windows. No new adverse events judged as being possibly or probably related to treatment were reported after the 6-month follow-up period.

[2] number of patients experiencing at least one occurrence within each time interval

* patient discontinued from study during the 6-month follow-up visit and subsequently had surgery for tennis elbow. No additional study data is available for this patient after the 6-month follow-up period.

At the time of the 12-week follow-up visit, all device related adverse events had resolved, except for one patient who had moderate elbow stiffness and mild swelling that was still ongoing at the time of the 6-month follow-up visit. This patient, who had an x-ray with normal findings at baseline and 12 weeks, was unresponsive to treatment and terminated study participation soon after the 6-month follow-up visit for surgery. There were no new device related adverse effects reported during the long-term (3-12month) follow-up period.

In addition to adverse events, lab values, physical exam results, X-rays, vital signs, and EKGs were assessed. No significant between group differences were observed.

L. 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 was not referred to the General and Plastic Surgery Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicated information previously reviewed by this panel.

FDA Decision:

This clinical study has demonstrated that use of the Siemens Sonocur Basic system for the treatment of patients with chronic lateral epicondylitis is a safe and effective alternative for patients who have a history of unsuccessful conservative treatments. The results show a good safety profile for the system and show that the system can be used to relieve pain and improve functional activity.

The preclinical and clinical data provide reasonable assurance that the Siemens SONOCUR Basic is safe and effective when used in accordance with the device labeling. In addition, the applicant's manufacturing facility was inspected and found to be in compliance with the Quality Systems Regulation (21CFR 820).

CDRH issued an approval order on July 19, 2002.

M. Approval specifications:

Directions for Use: see labeling

Hazard to Health from Use of Device: see Warnings, Precautions and Adverse Events section in the labeling

Conditions of Approval: see approval order