

K955666  
April 15, 1997

**510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: \_\_\_\_\_.

**1. Submitter's Identification:**

S&P Electrical Industries, Inc.  
D/B/A Electro-Med Health Industries  
11601 Biscayne Boulevard Suite 200A  
Miami, Florida 33181

**Date Summary Prepared:**

December 11, 1995

**2. Name of the Device:**

EGS4000 (High Voltage Pulsed Galvanic Stimulator)

**3. Predicate Device Information:**

EGS 300 (Portable High Voltage Pulsed Galvanic Stimulator)

Specification Developer:

S&P Electrical industries, Inc. D/B/A Electro-Med Health Industries

510(k) Numbers:

- K790847 -- Original submission-  
Substantial equivalence established
- K802107A-- Addition of TENS language and treatment  
of pain-  
Substantial equivalence established  
December 4, 1981 letter from Office of  
Compliance permitting reference to pain.
- K832371 -- Dental submission-  
Substantial equivalence again established  
and labeling accepted.

4. Device Description:

The EGS4000 is a Powered Muscle Stimulator and TENS device. It is a small battery operated device, as its predecessor, the EGS 300. The additional operational features include a second channel, a timer, additional switching rates, a change in lead wire receptacles -- to comply with the newest proposal on lead wire attachment. Additionally, independent intensity potentiometers are used. To enhance the versatility of the predicate this unit may also operate with an a/c adaptor. For recording time elapsed in usage, a data port allows for accessing the information. These last two features are performed with all the appropriate mechanisms to ensure patient safety.

The waveform, intensity available and pulse rates available are all as in the predicate device. Battery operation of the EGS4000 is performed with a 9 volt battery as opposed to the previous special 14.4 volt battery. This will allow the end user greater convenience while additionally allowing longer operating time with a single battery.

5. Intended Use:

Powered Muscle Stimulator Device:

- 1-Relaxation of Muscle Spasm.
- 2-Prevention or retardation of disuse atrophy.
- 3-Increasing local blood circulation.
- 4-Muscle re-education.
- 5-Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.
- 6-Maintaining or increasing range of motion.

TENS Device:

Symptomatic relief of chronic intractable pain.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

6. Comparison to Predicate Devices:

The predicate device, the EGS 300, is a battery operated "high voltage pulsed galvanic stimulator", also known as a neuromuscular stimulator or monophasic pulsatile current. This device replicates the waveform, in amplitude, duration and frequencies available. The predicate device uses knobs

(potentiometers) for patient controls. This device does the same. The predicate device utilizes a switch to change polarity of the active electrode, this device does the same.

The additional features on the EGS4000 are an additional output channel, a timer, a separate power On-Off switch, 2 additional switching rates, a change in lead wire receptacles--to comply with the newest proposal on lead wire attachment, operation on a 9V battery as opposed to a 14.4V dedicated battery, optional a/c adaptor and an elapsed time reading mechanism.

The obvious difference is one-third the weight and less than one-half the size.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The development has been with oscilloscope comparisons for waveforms and its characteristics. Timing was verified with timing checks as well as oscilloscope comparisons. Calculations for pulse charge, current density and power density were accomplished.

8. Discussion of clinical tests performed:

Non-Applicable

9. Conclusion:

The EGS4000 is presented for approval to meet today's changes in technology as well as newer FDA requirements for cables and lead wires. The changes and upgrades to the device meet both the FDA requirements and some market requirements. Function and output have not changed. Indications, contraindications and precautions are all updated.

**S&P ELECTRICAL INDUSTRIES, INC.**  
**D/B/A ELECTRO-MED HEALTH INDUSTRIES**

  
By: Phyllis Lehman, President

DATE: December 11, 1995