K951903

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 20 1996

Applicant name:	Empi, Inc.
Applicant address:	5255 East River Rd. Fridley, MN 55421
Contact person:	Stacy Mattson, Regulatory Affairs Manager
Phone:	612-586-7354
Date Prepared:	April 11, 1995
Classification Name:	Transcutaneous Electrical Nerve Stimulator
Common/Usual Name:	TENS unit
Trade/Proprietary Name:	Epix XL TENS Unit, Model 995
Equivalent Devices:	Empi Epix XL Model 989

Product/System Description

The Epix XL is a dual channel TENS device with four conventional modes of operation, eight pre-programmed regimens and a choice of two levels of output (0-40mA or 0-60mA). It is powered by a standard 9V alkaline or NiCad rechargeable battery. All operation modes produce the Empi Bi-Sourced® waveform.

The Epix XL System requires the use of a set of leadwires and one or two pair of cutaneous stimulation electrodes.

Intended Use:

The Epix XL TENS Unit is indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-trauma acute pain.

Comparison of Equivalent Devices to the New Device:

Summary of Technical Differences

The Epix XL Model 995 is technically identical to the Epix XL 989 with the exception of a change in the LED lights from red to green. No testing is needed to establish equivalence.

Summary of Performance - Nonclinical

The Epix XL Model 995 performs identically to the Epix XL Model 989 with the exception of an added function to prevent the stimulator from delivering current from a no output condition (no battery or device is turned OFF) to a rapid increase in current (fresh battery without turning the device OFF or manually turning the potentiometer up too quickly from start up of the device). This is an added feature which is required to meet international device standards. This function does not impact the performance of the device, thus does not require clinical testing to establish equivalence.

Product Verification and Validation

The functional testing was performed and the results analyzed against product specifications demonstrating that the product meets requirements and is acceptable for its intended use.

COMPARISON OF PRODUCT SPECIFICATIONS

The Epix XL Model 995 is substantially equivalent to the Epix XL Model 989. The similarities in the two products can be seen in the following chart.

Product Characteristics	Epix XL Model 989	Epix XL Model 995
Indications for Use	Symptomatic relief and management of chronic, intractable pain and adjunctiv treatment for post-surgical and post trauma acute pain.	Symptomatic relief and management o chronic, intractable pain and adjunctiv treatment for post-surgical and post trauma acute pain.
No. Of Output Channels	2	2
Standards	AAMI/ANSI NS4-1985 IEC 601-2-10 IEC 601-1-2	AAMI/ANSI NS4-1985 IEC 601-2-10 IEC 601-1-2
Control mechanism	Microprocessor, masked	Microprocessor, masked
Amplitude (voltage) Range	0-40Vpp (normal) 0-60Vpp (high)	0-40Vpp (normal) 0-60Vpp (high)
Maximum Output Voltage	120Vpp, 1MΩ	120Vpp, 1MΩ
Channel Interaction	≤ 5%	≤ 5%
Pulse Width	0-400μs at 50% of peak amplitude	0-400μs at 50% of peak amplitude
Waveform	Symmetrical, bi-phasic	Symmetrical, bi-phasic
Zero Net DC	yes; achieved through the transformer	yes; achieved through the transformer
Max. Charge per Pulse	20μC into a 500 Ohm load	20μC into a 500 Ohm load
Adjustable Pulse Rates	2, 10, 20, 40, 60, 80, 100, 150 Hz	2, 10, 20, 40, 60, 80, 100, 150 Hz
Standard Output Modes*	Continuous (C), Burst (B), Modulated Rate (R), Multi-Modulated (M)	Continuous (C), Burst (B), Modulated Rate (R), Multi-Modulated (M)
Preprogrammed Output Modes*	Extremely Low Frequency (ELF) Dual Pulse (DP) High Frequency (HF) Bi-Modal (BM) Ramped Burst (RB) Modulated Amplitude (MA) Alternating Ramped Burst (ARB) Random Modulation (RAM)	Extremely Low Frequency (ELF) Dual Pulse (DP) High Frequency (HF) Bi-Modal (BM) Ramped Burst (RB) Modulated Amplitude (MA) Alternating Ramped Burst (ARB) Random Modulation (RAM)
High Amplitude Shutdown (Output Interlock)	No	Yes
Housing Materials	ABS Plastic	ABS Plastic
Output Type	**constant voltage** **200Ω - 1kΩ**	**constant voltage** **200Ω - 1kΩ**
Minimum Electrode Size (active area)	**NeuroEase .25in^2 (1.6cm^2)**	**NeuroEase .25in^2 (1.6cm^2)**
Maximum RMS Current Density	**30.9mA/in2** **(4.88mA/cm2)**	**30.9mA/in2** **(4.88mA/cm2)**

Comparison of Product Specifications (cont.)

Product Characteristics	Epix XL Model 989	Epix XL Model 995
Maximum Power Density	243 W/in2 (38 mW/cm^2)	243 W/in2 (38 mW/cm^2)
Maximum Average Phase Current (specify load)	77mA, 200Ω load	77mA, 200Ω load
Maximum Enclosure Leakage Current	100μA	100μA
Automatic Overload Trip	NA	NA
Automatic No Load Trip	NA	NA
Patient Override Control	NA	NA
Max. Patient Leakage Current	100μA	100μA
Output Indicator	YES red	YES-green
Low Battery Indicator	YES, yellow	YES, yellow
Size	3.7in.x2.5in.x0.84in.	3.7in.x2.5in.x0.84in.
Weight	145 gm with battery	145 gm with battery
Power Source	9 V Alkaline Battery or equivalent Empi rechargeable battery	9 V Alkaline Battery or equivalent Empi rechargeable battery

The shaded areas show where there are differences between the two devices.