K951951

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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The assigned 510(k) number is: K951951

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.

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Date Prepared:	August 21, 1995
Classification Name:	Transcutaneous Electrical Nerve Stimulator (TENS) Powered Muscle Stimulator (NMES) External Functional Neuromuscular Stimulator (FES)
Common/Usual Name:	NMES/TENS/FES unit
Trade/Proprietary Name:	Empi Focus
Equivalent Devices:	Empi Focus Model 727 Empi Respond Select

Product Description:

The Focus Unit is a dual channel NMES/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 Focus Unit requires the use of a set of leadwires and one or two pair of electrodes. All NMES/TENS electrodes currently distributed by Empi are appropriate for use with the Focus. The use of other brands of electrodes is not recommended as the quality of those products is unknown and it has been observed that the quality of the electrode may impact the ability of the Focus to operate efficiently, i.e., if the electrode does not adhere to the skin current will not be delivered.

Intended Use:

As a TENS device, the Focus is indicated for the following conditions:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment for post-surgical and post-trauma acute pain

As a NMS/NMES device, the Focus is indicated for the following conditions:

- relaxation of muscle spasm
- prevention or retardation of disuse atrophy
- increasing local blood circulation
- muscle re-education
- prevention of venous thrombosis of the calf muscles immediately after surgery
- maintaining or increasing range of motion

As a FES device, the Focus is indicated for the following condition:

- stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait

Comparison of Equivalent Devices to the New Device:

The Focus Model 795 is technically identical to the Focus 727 with the exception of a change in the LED lights from red to yellow. No testing is needed to establish equivalence.

The Focus Model 795 performs identically to the Focus 727 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 "safety" 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.

The Focus 795 also has a new indication for use, gait training, which makes the Focus indications for use equivalent to the indications for the Respond Select. This new indication is supported by the fact that these two products' specifications are similar enough to be considered equivalent. See the comparison chart for specification details.

Product Verification and Validation

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

Comparison of Product Specifications

See the following chart for details on the similarities and differences of the two predicate devices and the Focus device.

COMPARISON OF PRODUCT SPECIFICATIONS

Product Characteristics	Focus Model 797	Focus Model 795	Respond Select
No. Of Output Channels	2	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	AAMI/ANSI NS4-1985 IEC 601-2-10 IEC 601-1-2
Current Range	0-60mA (normal) 0-100mA (high)	0-60mA (normal) 0-100mA (high)	0-100 mA (alkaline) 0-90 mA (NiCd)
Maximum Output Voltage (1kΩ load)	± 100 V *	± 100 V *	± 100 V*
Channel Interaction	≤ 5%	≤ 5%	≤ 5%
Pulse Width	300μs at 50% of peak amplitude	300μs at 50% of peak amplitude	300μs at 50% of peak amplitude
Waveforms*	Symmetrical biphasic or balanced asymmetrical biphasic	Symmetrical biphasic or balanced asymmetrical biphasic	Symmetrical biphasic or balance asymmetrical biphasic
Zero Net DC	yes controlled by transformer	yes controlled by transformer	yes controlled by transformer
Maximum Phase Charge (1kΩ load)	30μC *	30μC *	30μC *
Pulse Rates	25, 30, 35, 45, 50, 80 Hz	25, 30, 35, 45, 50, 80 Hz	1-80 Hz
ON Times	2.5, 5, 10, 15, 20, 25, 30, 50 sec	2.5, 5, 10, 15, 20, 25, 30, 50 sec	2-60 sec, adjustable
OFF Times	0, 5, 10, 15, 20, 25, 30, 50 sec	0, 5, 10, 15, 20, 25, 30, 50 sec	2-120 sec, adjustable
Ramp Time	2 sec up, fixed 2 sec down, fixed disabled with remote switch	2 sec up, fixed 2 sec down, fixed disabled with the remote switch	.2 - 10 sec up, adjustable .1 - 5 sec down, adjustable .4 sec up for gait protocol 1 sec down for gait protocol
Cycling Modes	synchronous(S) or alternating(A)	synchronous(S) or alternating(A)	synchronous or asynchronous
Timing Control Modes	continuous, normal operation, 15 or 30min,	continuous, normal operation, 15 or 30min,	continuous, 15, 30, 60min.
Preprogrammed Regimens	8	8	4
High Output Shutdown (Output Interlock)	NO	YES	YES
Waveform Change Interlock	YES	YES	YES
Compliance Timer	NO	NO	YES
Accessories	Hand Held Remote or Heel Switch	Hand Held Remote or Heel Switch	Hand Held Remote or Heel Switch
Output Type	constant current 100Ω - 1kΩ	constant current 100Ω - 1kΩ	constant current 100Ω - 1kΩ
Minimum Electrode Size	Snapease: 0.79in^2(5.1cm^2)	Snapease: 0.79in^2(5.1cm^2)	Snapease: 0.79in^2(5.1cm^2)
Maximum RMS Current Density	27.7mA/in^2 *	27.7mA/in^2 *	27.7mA/in^2 *
Maximum Phase Amplitude (specify load)	100mA at 1kΩ *	100mA at 1kΩ*	100mA at 1kΩ*
Maximum Power Density	607 mW/in^2 *	607 mW/in^2 *	607 mW/in^2 *

COMPARISON OF PRODUCT SPECIFICATIONS (cont.)

Product Characteristics	Focus Model 727	Focus Model 795	Respond Select
Phase Duration Range	300 μsec	300 μsec	300 μsec
Interface Interval	500 μsec	500 μsec	30 μsec
Maximum Enclosure Leakage Current	100μA	100μA	100μA
Automatic Overload Trip	NA	NA	NA
Automatic No Load Trip	NA	NA	NA
Patient Override Control	NA	NA	NA
Max. Patient Leakage Current	100μA	100μA	100μA
Output Indicator	YES	YES	YES
Low Battery Indicator	YES	YES	YES
Size	3.7x2.5x0.84	3.7x2.5x0.84	6x3.58x1.38
Weight	145 gm with battery	145 gm with battery	9.3 oz w/o battery
Power Source	9 V Alkaline Battery	9 V Alkaline Battery	9 V Alkaline Battery
Controller	Microprocessor, masked	Microprocessor, masked	Application Specific Integrated Circuit
Housing Material	ABS Plastic	ABS Plastic	ABS Plastic
Indications for Use	As a TENS device, the 727 is indicated for the following conditions: • symptomatic relief and management of chronic, intractable pain • adjunctive treatment for post-surgical and post-trauma acute pain As a NMS/NMES device, the Focus is indicated for the following conditions: • relaxation of muscle spasm • prevention or retardation of disuse atrophy • increasing local blood circulation • muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • maintaining or increasing range of motion	As a TENS device, the 795 is indicated for the following conditions: • symptomatic relief and management of chronic, intractable pain • adjunctive treatment for post-surgical and post-trauma acute pain As a NMS/NMES device, the Focus is indicated for the following conditions: • relaxation of muscle spasm • prevention or retardation of disuse atrophy • increasing local blood circulation • muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • maintaining or increasing range of motion As a FES device, the Focus is indicated for the following condition: • stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait	As a NMS/NMES device, Respond Select is indicated for the following conditions: • relaxation of muscle spasm • prevention or retardation of disuse atrophy • increasing local blood circulation • muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • maintaining or increasing range of motion As a FES device, the Focus is indicated for the following condition: • stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait