



K112258

This 510k Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

Name: Anne-Marie Keenan
Address: Bio-Medical Research Ltd.,
Parkmore Business Park, West
Galway, Ireland
Telephone: +353 91 774300
Fax: +353 91 774302
E-Mail: akeenan@bmr.ie
Prepared: November ,2, 2011

2. Device Name and Regulation

Trade Name of Device: Neurotech Plus, Type 413
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Product Code: GZJ, NYN, IPF
Device Class: II

3. Identification of Equivalent Legally Marketed Device

510(k) Number: K082011
Manufacturer: Bio-Medical Research Ltd.
Trade Name: MediStim XP, Type 281

510(k) Number: K082011
Manufacturer: Bio-Medical Research Ltd.
Trade Name: MediTens XP, Type 458

510(k) Number: K061516
Manufacturer: Compex Technologies
Trade Name: Staodyn® Max, Model 4470

510(k) Number: K971437
Manufacturer: Murray Electronics
Trade Name: Bionicare Stimulator System Model Bio-1000

4. Description of Device

The Neurotech Plus is a portable, two-channel; battery operated system which can provide both Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS). The device is intended be available by prescription only. Included with the Neurotech Plus control unit, are a lead wire assembly, electrodes and instructions for use.

The Neurotech Plus contains ten program sets which have been each allocated an individual type number. Seven of these types offer a combination of NMES and TENS programs. There are two types which offer only NMES programs and one which has only TENS programs.

The lead-wire assembly contains the ID chip (EEPROM) that identifies the required program set. Each of the program set options are pre-programmed during manufacturing and no access to the configuration is available to either the end user or clinician. When each lead wire is connected to the unit and the outputs (A, B, C or D) to the electrodes, the two channels may be operated independently through the unit. Detailed diagrams for correct device usage and placement of the electrodes are available as part of the instructions for use.

5. Statement of Intended Use/Indications for Use

Intended Use: Dependent on the program chosen, the Neurotech Plus, Type 413 can deliver Neuromuscular Electrical Stimulation (NMES) for the activation of muscle for rehabilitation

and/or Transcutaneous Electrical Nerve Stimulation (TENS) for the activation of nerves for neuromodulation and management of pain.

Indications for Use:

Models 431, 432, 433, 434, 436, 439, & 440 offer a combination of NMES or TENS programs.

NMES Indications for Use

Maintain or increase the range of motion

Prevention or retardation of disuse atrophy

Re-educate muscles

Relax muscle spasms

Increase local blood circulation

Prevention of venous thrombosis of the calf muscles immediately after surgery

TENS Indications for Use

Symptomatic relief and management of chronic, intractable pain

Relief of pain associated with arthritis

Adjunctive treatment in the management of post-surgical and post-trauma pain

Adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee (models 431, 432, 433 only)

Models 437, 441 (NMES only indications for use)

Maintain or increase the range of motion

Prevention or retardation of disuse atrophy

Re-educate muscles

Relax muscle spasms

Increase local blood circulation

Prevention of venous thrombosis of the calf muscles immediately after surgery

Model 438 (TENS only indications for use)

Symptomatic relief and management of chronic, intractable pain

Relief of pain associated with arthritis

Adjunctive treatment in the management of post-surgical and post-trauma pain

Sale of the device has been restricted to sale under a prescription order from a licensed practitioner.

6. Summary of Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Neurotech Plus device. No new clinical tests have been submitted as part of this premarket notification.

The Neurotech Plus device complies with the following international standards:

- IEC 60601-1 (1998) + A1 (1991) + A2 (1995) Medical Electrical Equipment - Part 1: General Requirements for Safety.
- IEC 60601-2-10 (1987) + A1 (2001) Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
- IEC 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests
- I.S. EN ISO 14971 2007

6.1 Program Sets

Tables 6.1.1 to 6.1.10 show the program parameters for each model of the Neurotech Plus.

Table 6.1+1 Model 431	Screen Text	Intensity	Rate (Hz or pps)	Pulse Width (usec)	Cont (sec.)	Relax (sec.)	Ramp Up (sec.)	Ramp Down (sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adj	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time (see Note 1)	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time (see Note 1)						Open
2	P2	Adj	99 (see Note 1)	200					Burst Toggle – 4 Hz, 250 usec. Activation and output remains constant after pressing the burst button. Press Burst again to cancel. No ramp up/down will be implemented	Open
3	P3	Adj	Ch 1: 4 Ch 2: 125	200					Criss-cross Function, Burst – Ch1 125 Hz, 200 usec & Ch2 125 Hz, 200 usec. Activation and output remains constant for 10 minutes after burst button pressed. No ramp up/down will be implemented (See note 2)	Open
4	P4	Adj	4	250					Burst – 125 Hz, 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented	Open
5	P5	Adj	50	300	5	15	1.0	0.5	Trigger	30
6	P6	Adj	50	300	5	10	1.0	0.5	Trigger	30
7	P7	Adj	50	300	5	5	1.0	0.5	Trigger	30
8	P8	Adj	35	300	5	10	1.0	0.5	Trigger	30
9	P9	Adj	8	300	5	5	1.0	0.5	Trigger	20
10	P10	Adj	100	100	5	15	1.0	0.5		90
			70	200						10
			100	100						90
			70	200						20
			100	100	5	15	1.0	0.5		20
			100	100						90

Table 6.1.2 Model 432	Screen Text	Intensity	Rate (Hz or pps)	Pulse Width (usec)	Contract (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adj	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time						Open
2	P2	Adj	99	200					Burst –4Hz, 250 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented	Open
3	P3	Adj	Ch 1: 4 Ch 2: 125	200					Criss-cross Function, Burst – Ch1 125 Hz, 200 usec & Ch2 125 Hz, 200 usec. Activation and output remains constant for 10 minutes after burst button pressed. No ramp up/down will be implemented. (See note 2)	Open
4	P4	Adj	4	250					Burst –125Hz, 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented	Open
5	P5	Adj	50	300	5	15	1.0	0.5	Trigger	30
6	P6	Adj	50	300	5	10	1.0	0.5	Trigger	30
7	P7	Adj	50	300	5	5	1.0	0.5	Trigger	30
8	P8	Adj	35	300	5	10	1.0	0.5	Trigger	20
9	P9	Adj	8	300	5	5	1.0	.5	Trigger	20
10	P10	Adj	100	100						70
			70	200	5	15	1.0	0.5		10
			100	100						70
			70	200	5	15	1.0	0.5		20
			100	100						70

Table 6.1.3 Model 433	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (increases) between 125 to 4 in 12 second cycle - remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle-- remains at 150 for 3 seconds and 250 for 3 seconds of cycle time						Open
2	P2	Adjustable	125	175					Burst - Frequency of 4 Hz, pulse width of 250 usec. Activation and output remains constant while pressing burst button. Will ramp down over 3 sec. and up over 3 sec.	Open
3	P3	Adjustable	4	250					Burst - Frequency of 125 Hz, pulse width of 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented.	Open
4	P4	Adjustable	50	300	5	15	1.0	0.5	Trigger	30
5	P5	Adjustable	50	300	5	10	1.0	0.5	Trigger	30
6	P6	Adjustable	50	300	5	5	1.0	0.5	Trigger	30
7	P7	Adjustable	35	300	5	10	1.0	0.5	Trigger	30
8	P8	Adjustable	8	300	5	5	1.0	0.5	Trigger	20
9	P9	Adjustable	100	100						70
10	P10	Adjustable	70	200	5	15	1.0	0.5		20

Table 6.1.4 Model 434	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	80	120	Continuous Stimulation		2			Open
2	P2	Adjustable	2	180	Continuous Stimulation		2			Open
3	P3	Adjustable	80	70 - 120	Continuous Stimulation		2			Open
4	P4	Adjustable	80/2	180	Continuous Stimulation		2			Open
5	P5	Adjustable	9/2	300	Continuous Stimulation		2			20
6	P6	Adjustable	8	300	5	5	1.0	0.5	Trigger	20
7	P7	Adjustable	35	300	5	10	1.0	0.5	Trigger	30
8	P8	Adjustable	50	300	5	15	1.0	0.5	Trigger	30
9	P9	Adjustable	50	300	5	10	1.0	0.5	Trigger	30
10	P10	Adjustable	50	300	5	5	1.0	0.5	Trigger	30

Table 6.1.5 Model 436	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time	NA	NA	NA	NA	None	Open
2	P2	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	50 to 100; modulates (increases) between 50 to 100 in 12 second cycle – remains at 50 for 3 seconds and 100 for 3 seconds of cycle time	NA	NA	NA	NA	None	Open
3	P3	Adjustable	125	150	NA	NA	NA	NA	Burst – Frequency is 80hz, pulse width 300 usec with 8 pulses per burst; 2 bursts per second. 12 second cycle time – 2 seconds modulation from normal to burst, 8 seconds at burst, 2 seconds modulating from burst to normal. Frequency will increment/decrement during the transition to/from burst.	Open
4	P4	Adjustable	80	300	10	25 (Remove Beep)	1.5	1.5	Trigger	30
5	P5	Adjustable	50	300	10	20 (Remove Beep)	1.5	1.5	Trigger	30
6	P6	Adjustable	35	300	5	5	1.5	1.5	Trigger	30

Table 6.1.6 Model 437	Duration	Frequency	Pulse Width	Ramp-Up time	Contract Time	Ramp Down Time	Relax time
Program 1	20 minutes	60Hz	200□s	2seconds	3 seconds	2 seconds	5 seconds
Program 2	25 minutes	55Hz	225□s	2seconds	3 seconds	2 seconds	5 seconds
Program 3	30 minutes	55Hz	250□s	2seconds	3 seconds	2 seconds	5 seconds
Program 4	40 minutes	50Hz	270□s	2seconds	3 seconds	2 seconds	5 seconds

Table 6.1.7 Model 438	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Pulse	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time	NA	45
2	P2	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	50 to 100; modulates (increases) between 50 to 100 in 12 second cycle – remains at 50 for 3 seconds and 100 for 3 seconds of cycle time	NA	45
3	P3	Adjustable	125	175	NA	45
4	P4	Adjustable	4	250	NA	45
5	P5	Adjustable	Channel 1 – 4 Channel 2 – 125	175	NA	45
6	P6	Adjustable	80	175	8 pulses per burst; 2 bursts per second	45
7	P7	Adjustable	125 to 50; modulates (decreases) between 125 and 50 in 8 second cycle (4/4)	175	NA	45
8	P8	Adjustable	125	250 to 150; modulates (decreases) between 250 and 150 in 8 second cycle (4/4)	NA	45
9	P9	Adjustable	125 to 50; modulates (decreases) between 125 to 50 in 6 second cycle (3/3)	50 to 100; modulates (increases) between 50 to 100 in 6 second cycle (3/3)	NA	45
10	P10	Adjustable	125 to 50; modulates (decreases) between 125 and 50 in 10 second cycle (5/5)	150 to 250; modulates (increases) between 150 and 250 in 10 second cycle (5/5)	NA	45

Table 6.1.8 Model 439	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	50	300	5	5	1.0	0.5	Trigger	30
2	P2	Adjustable	50	300	10	10	1.0	1.0	Trigger	30
3	P3	Adjustable	50	300	10	20	1.5	1.0	Trigger	30
4	P4	Adjustable	50	300	10	30	1.5	1.0	Trigger	30
5	P5	Adjustable	35	250	8	25	1.5	1.0	Trigger	30
6	P6	Adjustable	35	300	5	5	1.0	1.0	Trigger	30
7	P7	Adjustable	10	250	10	10	1.5	1.0	Trigger	30
8	P8	Adjustable	4	250					Burst -125 Hz, 175 usec. Activation and output remains constant while pressing burst button. Will ramp up over 3 sec. and down over 3 sec	45
9	P9	Adjustable	125	175					No-trigger	45
10	P10	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle - remains at 125 for 3 sec. and 4 for 3 sec. of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 sec. cycle - remains at 150 for 3 sec. and 250 for 3 sec. of cycle time					No-trigger	45

Table 6.1.9 Model 440	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle - remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle - remains at 150 for 3 seconds and 250 for 3 seconds of cycle time						Open
2	P2	Adjustable	99 to 50; modulates (decreases) between 99 and 50 in 8 second cycle (4/4)	150 to 250; modulates (increases) between 150 to 250 in 8 second cycle (4/4)						Open
3	P3	Adjustable	125	175					Criss-cross Function (See note 3)	Open
4	P4	Adjustable	4	250						
5	P5	Adjustable	50	300	5	10	1.0	0.5	Trigger	30
6	P6	Adjustable	50	300	10	10	1.0	0.5	Trigger	30
7	P7	Adjustable	50	300	10	20	1.0	0.5	Trigger	30
8	P8	Adjustable	50	300	10	30	1.0	0.5	Trigger	30
9	P8	Adjustable	35	300	5	5	1.0	0.5	Trigger	20
10	P10	Adjustable	10	300	10	10	1.0	0.5	Trigger	20

Table 6.1.10 Model 441	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	50	300	5	10	1.0	0.5	Trigger	20
2	P2	Adjustable	50	300	10	10	1.0	0.5	Trigger	20
3	P3	Adjustable	50	300	10	20	1.0	0.5	Trigger	20
4	P4	Adjustable	50	300	10	30	1.0	0.5	Trigger	20
5	P5	Adjustable	35	300	5	5	1.0	0.5	Trigger	20
6	P6	Adjustable	4	300	Continuous Stimulation				No-Trigger	20
7	P7	Adjustable	10	300	20	5	1.5	0.5	Trigger	20
8	P8	Adjustable	70	300	10	50	1.0	0.5	Trigger	20
9	P9	Adjustable	99	300	5	30	1.0	0.5	trigger	30

7. Substantial Equivalence Comparison Tables

Each model of the Neurotech Plus, Type 413 device has been compared to it's predicate device at the worst case program. Based on comparative analysis carried out between the proposed Neurotech Plus and the listed predicates, we believe that the proposed device is as safe, as effective and performs as well or better than the listed predicates.

Table 7.1				
Mode or Program Name (For calculation of maximum rms current, and power density)	Neurotech Plus Model 431	Prediccate Device Staedyn Max K061516	Prediccate Bioncare K971437	Prediccate MediTens K082011
	Plan 3 (Highest Output)	Program E. (Highest output)	Only has 1 mode	Program 3 99Hz, 150µS
Waveform (e.g pulsed monophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Monophasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	Rectangular, with interphase interval	Rectangular	Exponential, Spike	Rectangular, with interphase interval
Maximum Output Voltage (volts)(+/- 10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	12V 500Ω	37.5V @ 500 Ω
	75.0V @ 2 kΩ	Not available	Not available	70.0V @ 2 kΩ
	70.3V @ 10 kΩ	Not available	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	24mA @ 500Ω	75.0mA @ 500 Ω
	37.5mA @ 2 kΩ	Not available	Not available	35.0mA @ 500 Ω
	7.0mA @ 10 kΩ	Not available	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)	7.8V @ 500 Ω	8.9V @ 500 Ω	4.3V Estimated assuming a square pulse shape 0.64ms	6.5V @ 500Ω
	16.8V @ 2 kΩ	Not available	Not available	14.2V @ 2kΩ
	7.9V @ 10 kΩ	Not available	Not available	4.95V @ 10kΩ
RMS Output Current (specify units)(+/- 10%)	15.7mA @ 500 Ω	17.8mA @ 500 Ω	8.6mA	13mA @ 500Ω
	8.4mA @ 2 kΩ	Not available	Not available	7.1mA @ 2kΩ
	0.8mA @ 10 kΩ	Not available	Not available	0.5mA @ 10kΩ
Duration of primary (depolarizing) phase (usec)	250µS	60-350µS	640 µS	150µS
Pulse Duration (usec)	400-600µS (µS both phases + 100µS interphase delay)	700µS (350 µS both phases)	640 µS	400µS
Frequency (Hz) or Rate (pps)	4 to 125Hz	80 to 125 Hz	100 Hz	Both phases 4 to 99 Hz
For multiphasic waveforms only:	Symmetrical phases?	Yes	N/A	Yes
	Phase duration (include	100 to 250µS	60-350µS	100 to 150µS

Table 7.1		Neurotech Plus Model 431	Predicate Device Staudyn Max K061516	Predicate Bionicare K971437	Predicate MediTens K082011
Net Charge (microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	units) state range, if applicable)(both phases, if asymmetrical)	0 uC @ 500 Ω	0 uC @ 500 Ω	21 uC @ 500Ω	0 uC @ 500 Ω
		Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.		Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)		10.5 to 17.5 uC @ 500 Ω	9 to 21 uC @ 500 Ω	21 uC @ 500Ω	7.5 to 11.25 uC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s)		0.80mA/cm ² (T=1sec)	Program E Using 2" square electrode =17.8 mA/25 cm ² = 0.71 mA/ cm ²	0.08 mA/ cm ² i.e. 8.6mA/108 cm ² Using 12 x 9 cm electrodes	0.672mA/cm ² 5cm round electrode)
Maximum Average Current (average absolute value), mA { @ 500 Ω }		3.5mA	5.3mA	2.1mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }		6.2mW (T=1sec) 50mm round electrode	6.3 mW/cm ² Program E Using 2" square electrode	0.34 mW/cm ²	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	8	N/A	N/A
	(b) Bursts per second	N/A	2	N/A	N/A
	(c) Burst duration (seconds)	N/A	0.09	N/A	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A	.18	N/A	N/A
ON Time (seconds)		N/A	N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A	N/A

Table 7.2		Neurotech Plus Model 432	Predicate Device Staudyn Max K061516	Predicate Bioncare K971437	Predicate MedTens K082011
Mode or Program Name	Plan 3	Program E (highest output)	Only has 1 mode	Program 3 (99Hz, 150µS)	
Waveform (e.g pulsed monophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Monophasic	Pulsed, symmetric, biphasic	
Shape (e.g rectangular, spike, rectified sinusoidal)	Rectangular, with interphase interval	Rectangular	Exponential, Spike	Rectangular, with interphase interval	
Maximum Output Voltage (volts)(+/- 10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	12V 500Ω	37.5V @ 500 Ω	
	75.0V @ 2 kΩ	Not available	Not available	70.0V @ 2 kΩ	
	70.3V @ 10 kΩ	Not available	Not available	71.8V @ 10 kΩ	
Maximum Output Current (specify units)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	24mA @ 500Ω	75.0mA @ 500 Ω	
	37.5mA @ 2 kΩ	Not available	Not available	35.0mA @ 500 Ω	
	7.0mA @ 10 kΩ	Not available	Not available	7.0mA @ 10 kΩ	
RMS Output Voltage (volts)(+/- 10%)	7.8V @ 500 Ω	8.9V @ 500 Ω	4.3V Estimated assuming a square pulse shape 0.64ms	6.5V @ 500Ω	
	16.8V @ 2 kΩ	Not available	Not available	14.2V @ 2kΩ	
	7.9V @ 10 kΩ	Not available	Not available	4.95V @ 10kΩ	
RMS Output Current (specify units)(+/- 10%)	15.7mA @ 500 Ω	17.8mA @ 500 Ω	8.6mA	13mA @ 500Ω	
	8.4mA @ 2 kΩ	Not available	Not available	7.1mA @ 2kΩ	
	0.8mA @ 10 kΩ	Not available	Not available	0.5mA @ 10kΩ	
Duration of primary (depolarizing) phase (usec)	150-250µS	60-350µS	640 µS	150µS	
Pulse Duration (usec)	400-600µS (µS both phases + 100µS interphase delay)	700µS (350 µS both phases)	640 µS	400µS	
Frequency (Hz) or Rate (pps)	4-125Hz	80 to 125 Hz	100 Hz	4 to 99 Hz	
For multiphasic waveforms only:	Symmetrical phases? Yes	N/A	No	Yes	
	Phase duration (include units) state range, if	60-350µS	N/A	100 to 150µS	

Table 7.2		Neurotech Plus Model 432	Predicate Device Staodyn Max K061516	Predicate Bionicare K971437	Predicate MediTens K082011
applicable/both phases, if asymmetrical)	Net Charge (microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	0 uC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	0 uC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	21 uC @ 500Ω	0 uC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
	Maximum Phase Charge (uC)	14.0 uC @ 500 Ω	9 to 21 uC @ 500 Ω	21 uC @ 500Ω	7.5 to 11.25 uC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) (@ 500 Ω Where T is the output duration)	0.80mA/cm ² (T=1sec)	<u>Program E</u> Using 2" square electrode = 17.8 mA/25 cm ² = 0.71 mA/cm ²	0.08 mA/cm ² i.e. 8.6mA/108 cm ² Using 12 x 9 cm electrodes	0.672mA/cm ² 5cm round electrode)	
Maximum Average Current (average absolute value), mA (@ 500 Ω)	3.5mA	5.3mA	2.1mA	2.25mA	
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) (@ 500 Ω Where T is the output duration)	6.2mW (T=1sec)	6.3 mW/cm ² <u>Program E</u> Using 2" square electrode	0.34 mW/cm ²	4.4mW/cm ² 50mm round electrode	
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts	8	N/A	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
	(b) Bursts per second	N/A	2	N/A	N/A
	(c) Burst duration (seconds)	N/A	0.09	N/A	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A	.18	N/A	N/A
ON Time (seconds)	N/A	N/A	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A	N/A	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A	N/A

Table 7.3		Neurotech Plus Model 433	Predicate Device Staedyn Max K061516	Predicate Bioncare K971437	Predicate MediTens K082011
Mode or Program Name		Plan 2	Program E (Highest output)	Only has 1 mode	Program 3 99Hz, 150µS
Waveform (e.g pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Monophasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Rectangular, with interphase interval	Rectangular	Exponential, Spike	Rectangular, with interphase interval
Maximum Output Voltage (volts) (+/- 10%)		35.0V @ 500 Ω	30.0V @ 500 Ω	12V 500Ω	37.5V @ 500 Ω
		75.0V @ 2 kΩ	Not available	Not available	70.0V @ 2 kΩ
		70.3V @ 10 kΩ	Not available	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units) (+/- 10%)		70.0mA @ 500 Ω	60.0 mA @ 500 Ω	24mA @ 500Ω	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available	Not available	35.0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)		7.3V @ 500 Ω	8.9V @ 500 Ω	4.3V Estimated assuming a square pulse shape 0.64ms	6.5V @ 500Ω
		15.7V @ 2 kΩ	Not available	Not available	14.2V @ 2kΩ
		7.9V @ 10 kΩ	Not available	Not available	4.95V @ 10kΩ
RMS Output Current (specify units)(+/- 10%)		14.6mA @ 500 Ω	17.8mA @ 500 Ω	8.6mA	13mA @ 500Ω
		7.8mA @ 2 kΩ	Not available	Not available	7.1mA @ 2kΩ
		0.8mA @ 10 kΩ	Not available	Not available	0.5mA @ 10kΩ
Duration of primary (depolarizing) phase (usec)		150-250µS	60-350µS	640 µS	150µS
Pulse Duration (usec)		400-600µS (µS both phases + 100µS interphase delay)	700µS (350 µS both phases)	640 µS	400µS Both phases
Frequency (Hz) or Rate (pps)]		4-125Hz	80 to 125 Hz	100 Hz	4 to 99 Hz
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes		Yes
	Phase duration (include units) state range, if	60-350µS	N/A		100 to 150µS

Table 7.3		Neurotech Plus Model 433	Predicate Device Staudyn Max K061516	Predicare Bionicare K971437	Predicare MediTens K082011
	applicable (both phases, if asymmetrical)				
	Net Charge (microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	0 uC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	0 uC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	21 uC @ 500Ω	0 uC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
	Maximum Phase Charge (uC)	12.3 uC @ 500 Ω	9 to 21 uC @ 500 Ω	21 uC @ 500Ω	7.5 to 11.25 uC @ 500 Ω
	Maximum Current Density (mA/cm ² , r.m.s) (@ 500 Ω Where T is the output duration)	0.75mA/cm ² (T=1sec)	<u>Program E</u> Using 2" square electrode = 17.8 mA/25 cm ² = 0.71mA/ cm ²	0.08 mA/ cm ² i.e. 8.6mA/108 cm ² Using 12 x 9 cm electrodes	0.672mA/cm ² 5cm round electrode)
	Maximum Average Current (average absolute value), mA (@ 500 Ω)	3.06mA	5.3mA	2.1mA	2.25mA
	Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) (@ 500 Ω Where T is the output duration)	5.5mW (T=1sec)	6.3 mW/cm ² <u>Program E</u> Using 2" square electrode	0.34 mW/cm ²	4.4mW/ cm ² 50mm round electrode
	Burst Mode (i.e., pulse trains):	N/A Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts	8	N/A	N/A Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
	(b) Bursts per second	N/A	2	N/A	N/A
	(c) Burst duration (seconds)	N/A	0.09	N/A	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A	.18	N/A	N/A
	ON Time (seconds)	N/A	N/A	N/A	N/A
	OFF Time (seconds)	N/A	N/A	N/A	N/A
	Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A

Table 7.4		Neurotech Plus Model 434	Predicate Device Steadyn Max K061516	Predicate Device MediTens K082011
Mode or Program Name		Plan 4	Program E (Highest output)	Program 3 (99Hz, 150µS)
Waveform (e.g pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval
Maximum Output Voltage (volts) (+/- 10%)		35.0V @ 500 Ω	30.0V @ 500 Ω	37.5V @ 500 Ω
		75.0V @ 2 kΩ	Not available	70.0V @ 2 kΩ
		70.3V @ 10 kΩ	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units) (+/- 10%)		70.0mA @ 500 Ω	60.0 mA @ 500 Ω	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available	35.0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	7.0mA @ 10 kΩ
-RMS Output Voltage (volts) (+/- 10%)		5.4V @ 500 Ω	8.9V @ 500 Ω	6.5V @ 500Ω
		11.6V @ 2 kΩ	Not available	14.2V @ 2kΩ
		6.3V @ 10 kΩ	Not available	4.95V @ 10kΩ
RMS Output Current (specify units) (+/- 10%)		10.8mA @ 500 Ω	17.8mA @ 500 Ω	13mA @ 500Ω
		5.8mA @ 2 kΩ	Not available	7.1mA @ 2kΩ
		0.6mA @ 10 kΩ	Not available	0.5mA @ 10kΩ
Duration of primary (depolarizing) phase (µsec)		120-180µS	60-350µS	150µS
Pulse Duration (µsec)		340-460µS (µS both phases + 100µS interphase delay)	700µS (350 µS both phases)	400µS
Frequency (Hz) or Rate (pps)]		2-80Hz	80 to 125 Hz	4 to 99 Hz
For multiphasic waveforms only:		Yes	Yes	Yes
Symmetrical phases?		Yes	Yes	Yes
Phase duration (include units) state range, applicable)(both phases, if asymmetrical)		100 to 250µS	60-350µS	100 to 150µS
Net Charge(microcoulombs (µC) per pulse) (if zero, state method of achieving zero net charge.)		0 µC @ 500 Ω Symmetric, biphasic and leading polarity	0 µC @ 500 Ω Symmetric, biphasic and	0 µC @ 500 Ω Symmetric, biphasic and leading

	alternates for each successive pulse.	leading polarity alternates for each successive pulse.	polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	10.5uC @ 500 Ω	9 to 21 uC @ 500 Ω	7.5 to 11.25 uC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) { @ 500 Ω Where T is the output duration }	0.55mA/cm ² (T=1sec)	Program E Using 2" square electrode = 17.8 mA/25 cm ² = 0.71 mA/cm ²	0.672mA/cm ² 5cm round electrode)
Maximum Average Current (average absolute value), mA { @ 500 Ω }	1.68mA	5.3mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }	3.0mW (T=1sec)	6.3 mW/cm ² Program E Using 2" square electrode	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):	N/A	8	N/A
(a) Pulses per burst	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts		Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second		2	
(c) Burst duration (seconds)		0.09	
(d) Duty Cycle [Line (b) x Line (c)]		.18	
ON Time (seconds)	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A

Table 7.5		Neurotech Plus Model 436	Predicate Device Stadydynam Max K061516	Neurotech Plus Model 436	Predicate Device MedStim XP K082011
Mode or Program Name		Plan 3 (TENS)		Plan 4 (NMES)	
Waveform (e.g pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval	Rectangular, with interphase interval
Maximum Output Voltage (volts)(+/- 10%)		35.0V @ 500 Ω	30.0V @ 500 Ω	35.0V @ 500 Ω	37.5V @ 500 Ω
		75.0V @ 2 kΩ	Not available	75.0V @ 2 kΩ	70.0V @ 2 kΩ
		70.3V @ 10 kΩ	Not available	70.3V @ 10 kΩ	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)		70.0mA @ 500 Ω	60.0 mA @ 500 Ω	70.0mA @ 500 Ω	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available	37.5mA @ 2 kΩ	35.0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	7.0 mA @ 10 kΩ	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)		6.8V @ 500 Ω	Not available	7.7V @ 500 Ω	6.5 V @ 500 Ω
		14.5V @ 2 kΩ	Not available	16.4V @ 2 kΩ	12.1V @ 2 kΩ
		7.8V @ 10 kΩ	Not available	6.3V @ 10 kΩ	7.1V @ 10 kΩ
RMS Output Current (specify units)(+/- 10%)		13.6mA @ 500 Ω	Not available	15.3mA @ 500 Ω	13.0mA @ 500 Ω
		7.3mA @ 2 kΩ	Not available	8.2mA @ 2 kΩ	6.0mA @ 2 kΩ
		0.8mA @ 10 kΩ	Not available	0.6mA @ 10 kΩ	0.7mA @ 10 kΩ
Duration of primary (depolarizing) phase (usec)		50-250uS	60-350uS	300uS	150-300uS
Pulse Duration (usec)		200-600uS (uS both phases + 100uS interphase delay)	700uS (350 uS both phases)	600 uS (100 uS both phases + 100uS interphase delay)	400-700uS(100 uS both phases + 100uS interphase delay)
Frequency (Hz) or Rate (pps)]		4-125Hz	Not available	35-80Hz	2-100Hz
For multiphasic waveforms only:					
		Symmetrical phases?	N/A	N/A	N/A
		Phase duration (include units) state range, if applicable(both phases, if asymmetrical)	N/A	N/A	N/A
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)		0 μC @ 500 Ω	0 μC @ 500 Ω	0 μC @ 500 Ω	0 μC @ 500 Ω
		Symmetric, biphasic and leading polarity alternates	Symmetric, biphasic and leading polarity alternates	Symmetric, biphasic and leading polarity alternates	Symmetric, biphasic and leading polarity alternates

Table 7.5		Neurotech Plus Model 436	Predicate Device Staudyn Max K061516	Neurotech Plus Model 436	Predicate Device MedStim XP K082011
		for each successive pulse.	for each successive pulse.	for each successive pulse.	for each successive pulse.
Maximum Phase Charge (uC)		10.5µC @ 500 Ω	Not available	21.0µC @ 500 Ω	21.0µC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) (@ 500 Ω Where T is the output duration)		0.69mA/cm ² (T=1sec)	Not available	0.78mA/cm ² (T=1sec)	mA/cm ² (T=1sec)
Maximum Average Current (average absolute value), mA (@ 500 Ω)		2.63mA	Not available	3.36mA	Not available
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) (@ 500 Ω Where T is the output duration)		4.7mW (T=1sec)	Not available	6.0mW (T=1sec)	Not available
Burst Mode (i.e., pulse trains):		(a) Pulses per burst	N/A	N/A	N/A
		(b) Bursts per second	N/A	N/A	N/A
		(c) Burst duration (seconds)	N/A	N/A	N/A
		(d) Duty Cycle [Line (b) x Line (c)]	N/A	N/A	N/A
ON Time (seconds)		N/A	N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A	N/A

Table 7.6		Predicate Device MediStim XP K082011
Mode or Program Name		Neurotech Plus Model 437
Waveform (e.g pulsed monophasic, biphasic)		Plan 3 (NMES) Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Pulsed, symmetric, biphasic
Maximum Output Voltage (volts)(+/- 10%)		Rectangular, with interphase interval 35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)		Rectangular, with interphase interval 37.5V @ 500 Ω 70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0 mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)		75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ 6.5 V @ 500 Ω 12.1V @ 2 kΩ 7.1V @ 10 kΩ
RMS Output Current (specify units)(+/- 10%)		13.0mA @ 500 Ω 6.0mA @ 2 kΩ 0.7mA @ 10 kΩ
Duration of primary (depolarizing) phase (usec)		150-300us
Pulse Duration (usec)		400-700us(100 uS both phases + 100µS interphase delay)
Frequency (Hz) or Rate (pps)]		50-60Hz 2-100Hz
For multiphasic waveforms only:		N/A
Symmetrical phases?		N/A
Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)		N/A
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)		0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)		21.0µC @ 500 Ω
Maximum Current Density (mA/cm², r.m.s) (@ 500 Ω Where T is the output duration)		0.59mA/cm ² (T=1sec)

Table 7.6		Neurotech Plus Model 437	Predicate Device MediStim XP K082011
Maximum Average Current (average absolute value), mA { @ 500 Ω }		1.93mA	Not available
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }		3.4mW (T=1sec)	Not available
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A
	(b) Bursts per second	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A	N/A
ON Time (seconds)		N/A	N/A
OFF Time (seconds)		N/A	N/A

Table 7.7		Predicate Device Stuodyn Max K061516
Mode or Program Name		Plan 8
Waveform (e.g pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Rectangular
Maximum Output Voltage (volts)(+/- 10%)		30.0V @ 500 Ω
		Not available
		Not available
Maximum Output Current (specify units)(+/- 10%)		60.0 mA @ 500 Ω
		Not available
		Not available
RMS Output Voltage (volts)(+/- 10%)		Not available
		Not available
		Not available
RMS Output Current (specify units)(+/- 10%)		Not available
		Not available
		Not available
Duration of primary (depolarizing) phase (usec)		60-350ns
Pulse Duration (usec)		700uS (350 uS both phases)
Frequency (Hz) [or Rate (pps)]		
For multiphasic waveforms only:		
	Symmetrical phases?	N/A
	Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	N/A
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)		0 μC @ 500 Ω
		Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)		
Maximum Current Density (mA/cm², r.m.s)		17.5μC @ 500 Ω
		0.89mA/cm ² (T=1sec)

{ @ 500 Ω Where T is the output duration }	
Maximum Average Current (average absolute value), mA { @ 500 Ω }	4.38mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area)	7.8mW (T=1sec)
{ @ 500 Ω Where T is the output duration }	
Burst Mode (i.e., pulse trains):	
(a) Pulses per burst	N/A
(b) Bursts per second	N/A
(c) Burst duration (seconds)	N/A
(d) Duty Cycle [Line (b) x Line (c)]	N/A
ON Time (seconds)	N/A
OFF Time (seconds)	N/A

Table 7.8		Neurotech Plus Model 439	Predicate Device Staodyn Max K061516	Predicate MedITens K082011
Mode or Program Name		Plan 9 (TENS)	Program E (Highest output)	Program 3
Waveform (e.g pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval
Maximum Output Voltage (volts) (+/- 10%)		35.0V @ 500 Ω	30.0V @ 500 Ω	37.5V @ 500 Ω
		75.0V @ 2 kΩ	Not available	70.0V @ 2 kΩ
		70.3V @ 10 kΩ	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units) (+/- 10%)		70.0mA @ 500 Ω	60.0 mA @ 500 Ω	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available	35.0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts) (+/- 10%)		6.8V @ 500 Ω	8.9V @ 500 Ω	6.5V @ 500Ω
		14.6V @ 2 kΩ	Not available	14.2V @ 2kΩ
		7.8V @ 10 kΩ	Not available	4.95V @ 10kΩ
RMS Output Current (specify units) (+/- 10%)		13.6mA @ 500 Ω	17.8mA @ 500 Ω	13mA @ 500Ω
		7.3mA @ 2 kΩ	Not available	7.1mA @ 2kΩ
		0.8mA @ 10 kΩ	Not available	0.5mA @ 10kΩ
Duration of primary (depolarizing) phase (usec)		150-250µs	60-350µs	150µs
Pulse Duration (usec)		400-600µs (µs both phases + 100µs interphase delay)	700µs (350 µs both phases)	400µs
Frequency (Hz) or Rate (pps)		4-125Hz	80 to 125 Hz	Both phases 4 to 99 Hz
For multiphasic waveforms only:		Yes	Yes	Yes
Symmetrical Phases?		Yes	Yes	Yes
Phase Duration		100 to 250µs	60-350µs	100 to 150µs
Net Charge (microcoulombs (µC) per pulse) (if zero, state method of achieving zero net charge.)		0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (µC)		10.6µC @ 500 Ω	9 to 21 µC @ 500 Ω	7.5 to 11.25 µC @ 500 Ω

Table 7.8		Neurotech Plus Model 439	Predicate Device Staedyn Max K061516	Predicate MediTens K082011
Maximum Current Density (mA/cm ² , r.m.s) { @ 500 Ω Where T is the output duration }		0.70mA/cm ² (T=1sec)	Program E Using 2" square electrode =17.8 mA/25 cm ² = 0.71 mA/ cm ²	0.672mA/cm ² 5cm round electrode)
Maximum Average Current (average absolute value), mA { @ 500 Ω }		2.66mA	5.3mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }		4.7mW (T=1sec)	6.3 mW/cm ² Program E Using 2" square electrode	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):		N/A	8	N/A
(a) Pulses per burst		Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts		Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second			2	
(c) Burst duration (seconds)			0.09	
(d) Duty Cycle [Line (b) x Line (c)]			.18	
ON Time (seconds)		N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A
Additional Features (specify, if applicable)		N/A	N/A	N/A

Table 7.9	Neurotech Plus Model 440	Predicate Device Staodyn Max K061516	Predicate MediTens K082011
Mode or Program Name	Plan 9 (TENS)	Program E (Highest output)	Program 3 (99Hz, 150µs)
Waveform (e.g. pulsed monophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g. rectangular, spike, rectified sinusoidal)	Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval
Maximum Output Voltage (volts)(+/- 10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	37.5V @ 500 Ω
	75.0V @ 2 kΩ	Not available	70.0V @ 2 kΩ
	70.3V @ 10 kΩ	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	75.0mA @ 500 Ω
	37.5mA @ 2 kΩ	Not available	35.0mA @ 500 Ω
	7.0mA @ 10 kΩ	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)	6.8V @ 500 Ω	8.9V @ 500 Ω	6.5V @ 500Ω
	14.6V @ 2 kΩ	Not available	14.2V @ 2kΩ
	7.8V @ 10 kΩ	Not available	4.95V @ 10kΩ
RMS Output Current (specify units)(+/- 10%)	13.6mA @ 500 Ω	17.8mA @ 500 Ω	13mA @ 500Ω
	7.3mA @ 2 kΩ	Not available	7.1mA @ 2kΩ
	0.8mA @ 10 kΩ	Not available	0.5mA @ 10kΩ
Duration of primary (depolarizing) phase (usec)	150-250µs	60-350µs	150µs
Pulse Duration (usec)	400-600µs (µs both phases + 100µs interphase delay)	700µs (350 µs both phases)	400µs
Frequency (Hz) or Rate (pps)	4-125Hz	80 to 125 Hz	4 to 99 Hz
For multiphasic waveforms only:	Yes	Yes	Yes
	100 to 250µs	60-350µs	100 to 150µs
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	0 µC @ 500 Ω	0 µC @ 500 Ω	0 µC @ 500 Ω
	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	10.6µC @ 500 Ω	9 to 21 µC @ 500 Ω	7.5 to 11.25 µC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) (@ 500 Ω Where T is the output duration)	0.70mA/cm ² (T= 1sec)	Program E Using 2" square electrode = 17.8 mA/25 cm ²	0.672mA/cm ² 5cm round electrode)

Table 7.9	Neurotech Plus Model 440	Predicate Device Stadyn Max K061516 = 0.71mA/cm ² 5.3mA	Predicate MediTens K082011
Maximum Average Current (average absolute value), mA { @ 500 Ω }	2.66mA		2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }	4.7mW (T=1sec)	6.3 mW/cm ² Program E Using 2" square electrode	4.4mW/cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):	N/A	8	N/A
(a) Pulses per burst	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts		Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second		2	
(c) Burst duration (seconds)		0.09	
(d) Duty Cycle Line (b) x Line (c)		.18	
ON Time (seconds)	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A

Table 7.10		Predicate Device MediStim XP K082011
Mode or Program Name		Plan 9 (NMES)
Waveform (e.g pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Rectangular, with interphase interval
Maximum Output Voltage (volts) (+/- 10%)		37.5V @ 500 Ω 70.0V @ 2 kΩ 71.8V @ 10 kΩ
Maximum Output Current (specify units) (+/- 10%)		75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ
RMS Output Voltage (volts) (+/- 10%)		8.5V @ 500 Ω 18.3V @ 2 kΩ 7.0V @ 10 kΩ
RMS Output Current (specify units)(+/- 10%)		17.1mA @ 500 Ω 9.1mA @ 2 kΩ 0.7mA @ 10 kΩ
Duration of primary (depolarizing) phase (usec)		300uS
Pulse Duration (usec)		400uS (100 uS both phases + 100uS interphase delay)
Frequency (Hz) or Rate (pps)		10-99Hz
For multiphasic waveforms only:	Symmetrical phases?	N/A
	Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	N/A
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)		0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)		21.0μC @ 500 Ω

Maximum Current Density (mA/cm^2 , r.m.s) { @ 500 Ω Where T is the output duration }	0.87mA/cm ² (T=1sec)	
Maximum Average Current (average absolute value), mA { @ 500 Ω }	4.16mA	Not available
Maximum Average Power Density, (W/cm^2), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }	7.4mW (T=1sec)	Not available
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A
	(b) Bursts per second	N/A
	(c) Burst duration (seconds)	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A
ON Time (seconds)	N/A	N/A
OFF Time (seconds)	N/A	N/A



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Biomedical Research, LTD
c/o Ms. Anne-Marie Keenan
Quality & Regulatory Engineer
Parkmore Business Park West
Galway, Ireland

JAN - 9 2012

Re: K112258

Trade/Device Name: Neurotech Plus, Type 413
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ, NYN, IPF
Dated: November 30, 2011
Received: December 5, 2011

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

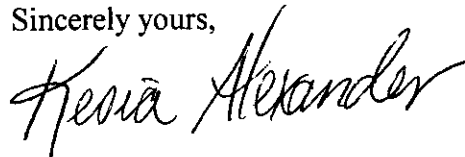
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



ja
Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112258

Device Name: Neurotech Plus, Type 413

Indications for Use: The Neurotech Plus device is indicated for the following:

In combination Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS) modes, models 431, 432, 433, 434, 436, 439 & 440:

NMES Indications	TENS Indications
Maintain or increase the range of motion	Symptomatic relief and management of chronic, intractable pain
Prevention or retardation of disuse atrophy	Relief of pain associated with arthritis
Re-educate muscles	Adjunctive treatment in the management of post-surgical and post-trauma pain
Relax muscle spasms	Adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee (models 431, 432 and 433 only)
Increase local blood circulation	
Prevention of venous thrombosis of the calf muscles immediately after surgery	

In Neuromuscular Electrical Stimulation (NMES) only mode, models 437 & 441:

NMES Indications
Maintain or increase the range of motion
Prevention or retardation of disuse atrophy
Re-educate muscles
Relax muscle spasms
Increase local blood circulation
Prevention of venous thrombosis of the calf muscles immediately after surgery

In Transcutaneous Electrical Nerve Stimulation (TENS) only mode, model 438:

TENS Indications
Symptomatic relief and management of chronic, intractable pain
Relief of pain associated with arthritis
Adjunctive treatment in the management of post-surgical and post-trauma pain

Prescription Use X AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
 Nose and Throat Devices

510(k) Number K112258