K041063

DEC - 1 2004

Attachment A

510(k) Summary of Safety and Effectiveness

Date Prepared:	April 19, 2004
Submitter:	Newwave Medical, LLC 620 Haggard ST. STE 614 Plano, TX 75074 (972) 516-8383
Contact Person:	Robert Armstrong
Trade (Proprietary) Name:	Smartwave MS 2000
Common/Classification Name:	Powered Muscle Stimulator
Device Classification:	Class II
Predicate Device:	**Staodyn**, Inc.
Description of Device:	The Smartwave MS 2000 Muscle Stimulator is a Square wave generator designed for neuromuscular electrical stimulation (NMES). The MS 2000 stimulates neuromuscular tissues through cutaneous electrodes connected by lead wires to the generator.
Statement of Intended Use:	Relaxation of muscle spasms. Prevention of 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.
Technological Characteristics:	The new device has the same Technological characteristics as the Predicate device. See table 1 (next Page) for a summary of the Technological characteristics of the New device in comparison to those of The predicate device.

Attachment A
Table 1
Comparison of the Smartwave MS 2000 and Staodyn EMS +2

	New Device	Marketed Device
1) 510 (k) Number	This Submission	K926510
2) Device Name	Smartwave MS 2000	EMS +2
3) Manufacturer	Newwave Medical, LLC	Staodyn Inc.
4) Power Source	9V	9V
Optional wall adapter	100-120vac, 50-60Hz	no
Method of line current Isolation	Transformer coupled	
Patient leakage current (w/adapter)		
Normal condition	3.2uA	
Single fault	6.5uA	
5) # of output modes	Pulsed DC, AC, Russian Stim	Pulsed DC, AC
6) # of output channels	1 or 2	1 or 2
Synchronous	yes	yes
Reciprocal	no	no
7) Computerized	no	no
8) Software Provided	no	no
9) Constant Current (±5%)	yes	yes
10) Constant Voltage	no	no
11) Max Output Current each channel (±5%)	57.2mA-500~ 17.8mA-2K~ 3.8mA-10K~	95.2mA-500~ 46.8mA-2K~ 9.63mA-10K~
12) Max Output Voltage baseline-to-peak	28.6V-500~ 35.5V-2K~ 38.3V-10K~	47.6V-500~ 93.6V-2K~ 96.3V-10K~
13) Channel isolation	Independent isolation transformer	Capacitor coupled
14) Line Current isolation	Transformer coupled	N/A
15) Automatic overload trip	no	no
16) Automatic no load trip	yes (when the unit is turned on, if it is not used, it will turn itself off after 10 minutes.)	no
17) Patient override control	yes (by turning off unit)	yes (by turning off unit)
18) Max leakage current (uA)		
chassis (input)	N/A	N/A
electrodes (output)	N/A	N/A
19) Indicator display	LCD	no
unit functioning	yes	yes (red LEDs)
low battery indicator	yes (Lo b displayed @ <6.0V)	yes (yellow LED on @ <6.0V)
intensity level	yes (0 to 35 displayed)	rotary dials
20) UL544	(complies with UL544 Safety Standard for Medical Equip.)	
21) Timer Settings (range) (±1%)	0-60 min., 0 is constant on	15, 30, 60 min. and constant on
22) Automatic shut off	yes	yes
23) Weight	6.24 oz.	9.8 oz.
24) Dimensions (in.)	4.68L x 2.77W x 1.01H	5.4L x 3.2W x 1.15H
25) Housing materials and construction	ABS plastic injection molded	ABS plastic vacuum molded

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2004

Mr. Robert Armstrong
President
Newwave Medical, LLC
620 Haggard Street, Suite 614
Plano, Texas 75074

Re: K041063
Trade/Device Name: Smartwave MS 2000
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: October 29, 2004
Received: October 29, 2004

Dear Mr. Armstrong:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041063

Device Name: Smartwave MS2000

Indications For Use:

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

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041063