K092990

5 10(k) Summary
AMD – 6605 TENS/NMES

Submitter's Name: Advantageous Medical Devices, LLC

Address: 1728 Virginia Beach Blvd.
Suite# 115
Virginia Beach, VA 23454

OCT 23 2009

Contact: John Herod
Phone: (757) 351-0832
Fax: (800) 715-4039

Summary Prepared: New - November 14, 2008

Trade Name: **AMD 6605**

Manufacture: Shenzhen Dongdixin Technology Co., LTD.
Address: No.3 Factory Building, Fanshenxusheng Industrial Estate Bao'an District, Shenzhen P.R. China. Zip: 518108

Common Name: For TENS function - TENS device
For NMES function – Powered Muscle Stimulator

Classification Name: For TENS functions:

Transcutaneous Electrical Nerve Stimulator for Pain Relief.
21 CFR 882.5890, Class II,
Product Code: GZJ
(Prescription) or Stimulator, Nerve, Transcutaneous, For Pain Relief.

Classification Name: For NMES functions:

Powered Muscle Stimulator for re-education of Muscles
21 CFR 890.5850, Class II,
Product Code: IPF;
(Prescription) or Stimulator, Nerve, Transcutaneous, muscle re-education

Predicate Device Identification:

21CFR:890.5850
Product Code: *IPF / GZJ*
Device Class: II
Legally Marketed Device: Elpha II 3000
Manufacturer: Danmeter A/S
K#: K032954

Device Description:

AMD 6605 TENS portion: is designed to provide electrical stimulation, for the following:

- Symptomatic relief and management of chronic (long-term), intractable pain and as an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain.

The AMD 6605 NMES portion: is a portable Neuromuscular Muscular Electrical Stimulator device for the following:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and
- Maintaining or increasing range of motion

The AMD 6605 is a 2 channel TENS/NMES stimulator device that is used to help reduce pain, with each channel being isolated from the other. The AMD 6605 is a programmable device that come equipped with 10 preset programs along with 10 user programs. The user programs are adjustable and can be changed to best help the patient at the doctor's recommendation and prescription settings. The program modes are preset programs that a clinician can conveniently choose from should they desire. This device has a special masking program to make the unwanted programs unavailable to the patients while locking the device in the needed relief setting. This way the patient does not receive the knowledge or ability to change the doctor's prescription settings without a clinician's consent. The AMD 6605 is programmed to default to program P-10 which contains the most common setting.

The device gives the clinician ability to store frequencies or to choose from a set of many frequencies that allow quick and easy selection, for prescription of stimulation regimen that can be later stored in any of the many available memory slots. However once the program is set the patients does not have the ability to alter the program from what the doctor or licensed practitioner has deemed to be the most appropriate program for their patient's needs.

The AMD 6605 has the following specifications: There is pulse mode with a bi-phase retangular pulse, the pulse frequency is 1Hz to 3.65KHz, the pulse width is 30uS to 300us, and the pulse amplitude is 140 levels(less than 70mA peak into 1000 ohms load to each channel). The power supply of AMD 6605 is 6.0V DC; this is supplied by four AAA type batteries.

AMD 6605 package is comprised of the following items:

1. One TENS/NMES unit powered by 4 AAA 1 .5V batteries.
2. Two UL industry standard wires for electrodes conforming to FDA standards,
3. Four standard commercially available round 50(mm) self adhesive electrodes.
4. One UL 110 battery rechargeable unit
5. Instruction manual.
6. Quick start instruction manual.
7. Full package carrying case.
8. Personal carrying device.

Waveform Description

See attached Waveform pages that show different waveforms that are available for different protocols as the physician/clinician sees to be most appropriate for the patient.

Note: In order to name these modes and variations, we simply label them as variations P1, P2, P3... P 10. All wave variations have same indications of use. See waveform charts enclosed.

Note: The AMD 6605 has been preset to default to the pre-programmed mode of P-1 0 and cannot be changed unless under the orders of the treating physician or medical practitioner. This was decided for simplicity in operation, training, and operation for the patient. The patient need only turn the unit on and turn the intensity up to the desired comfort level that is best relieving the pain symptoms. The characteristics of the device can be varied and changed however only if the other programs are unmasked or unhidden by the medical practitioner.

Indications for use

Indications for TENS function:

- Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain or post-traumatic acute pain.

Indications for NMES function:

- Relaxation of muscle spasms
- 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

There is no clinical basis or benefit for selecting one variation over the other. It is up to the physician to choose the correct placement, regimen and program to be used for chronic or acute pain relief along with whatever muscle function therapy that is being delivered to the patient..

It is AMD's belief that this should be for distribution by Rx only by order of a physician or a medical practitioner. The predicated devices that have been shown to be like products are marketed in the same manner.

This is a Class II medical device by FDA standards and believed to be the standard format that should be followed in classification and prescribing methods.

Intended use For TENS function:
The AMD 6605 TENS/NMES is an electrotherapy device that is used for the following:

- Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain or post-traumatic acute pain.

Intended use for NMES function:
The AMD 6605 TENS/NMES is indicated for along with the following:

- Relaxation of muscle spasms
- 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

The **AMD 6605 TENS/NMES** brings together similar **TENS** and **Powered Muscle Stimulator** functions from a previously cleared for market device; namely the **Elpha Model II3000.**

The AMD 6605 TENS/NMES device is based on and is virtually identical to the Predicate device.

Declaration of Conformity

Attached documentation with all Declaration of conformity paperwork has been included in the 510(k) submission that proves that this device is in conformity and upheld to the highest standards. The standards codes can be found in the Non-Clinical Data of this report.

Summary of Safety and Effectiveness

The AMD 6605 are substantially equivalent to the following device Elpha Model II3000 Manufactured by Danmeter A/S. The treatment system is substantially equivalent because of similar indication for use and unit characteristics.

The AMD 6605 does not raise new issues of safety and effectiveness based on their similarities.

This product has continually proven to be safe and effective and demonstrates that the product perform as intended.

Basis for substantial equivalence

AMD 6605 has basic technological characteristics that are substantially equivalent to the TENS and the EMS (Powered Muscle Stimulator) predicate devices. They all have preset output energy levels selectable by depression of a button. All units store and recall the desired treatment as selected by the physician or medical practitioner. All units have shrouded cables that comply with FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables".

The AMD 6605 is equivalent in function and intended use to the predicate device. Both offer similar user options and functions. The AMD 6605 offers a simplified user interface; however it does not have a frequency range as great as the predicate devices already in market.

510(k) Summary

Comparison:	AMD 6605	ELPHA II 3000
Intended Use:	**The AMD 6605 TENS/NMES is an electrotherapy device that is used for the following:** □ Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain. **The AMD 6605 TENS/NMES is indicated for along with the following:** □ Relaxation of muscle spasms □ Prevention or retardation of disuse atrophy □ Increasing local blood circulation □ Muscle re-education □ Immediate post-surgical stimulation of the calf muscle to prevent venous thrombosis □ Maintaining or increasing range of motion	**ELPHA II 3000 TENS/NMES is an electrotherapy device that is used for the following:** □ Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain. **ELPHA II 3000 TENS/NMES is indicated for along with the following:** □ Relaxation of muscle spasms □ Prevention or retardation of disuse atrophy □ Increasing local blood circulation □ Muscle re-education □ Immediate post-surgical stimulation of the calf muscle to prevent venous thrombosis □ Maintaining or increasing range of motion
Indications for use:	**The AMD 6605 TENS/NMES is an electrotherapy device that is used for the following:**	**ELPHA II 3000 TENS/NMES is an electrotherapy device that is used for the following:**
	□ Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain. **The AMD 6605 TENS/NMES is indicated for along with the following:** □ Relaxation of muscle spasms □ Prevention or retardation of disuse atrophy □ Increasing local blood circulation □ Muscle re-education □ Immediate post-surgical stimulation of the calf muscle to prevent venous thrombosis □ Maintaining or increasing range of motion	□ Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain. **ELPHA II 3000 TENS/NMES is indicated for along with the following:** □ Relaxation of muscle spasms □ Prevention or retardation of disuse atrophy □ Increasing local blood circulation □ Muscle re-education □ Immediate post-surgical stimulation of the calf muscle to prevent venous thrombosis □ Maintaining or increasing range of motion
Target population:	18 yrs of age and older	18 yrs of age and older
Human factors:	Identical	Identical
Contraindications for TENS/NMES:	Patients with pacemakers and heart conditions should NOT use Do NOT use stimulation over the carotids sinus nerves, the larynx or throat muscles Do NOT use stimulation trans-cerebrally. Do NOT use on undiagnosed pain or until etiology is established.	Patients with pacemakers and heart conditions should NOT use Do NOT use stimulation over the carotids sinus nerves, the larynx or throat muscles Do NOT use stimulation trans-cerebrally. Do NOT use on undiagnosed pain or until etiology is established.

The above comparisons are identical in every way for both products for intended use, indications and contraindications, target population, human factors that should be put into consideration when considering substantial equivalence of the above applied and the predicate devices according to FDA 510(k) requirements.

Design:

Type	TENS/NMES product	TENS/NMES product
Number of channels	2 channel (independently controlled)	2 channel (independently controlled)
Electrodes	2 electrodes per channel (4 total)	2 electrodes per channel (4 total)
Electrode type	2" round self-adhering reusable Amgel based electrodes, FDA approved	2" round self-adhering reusable Amgel based electrodes
Wave Form	Monophasic rectangular wave-form single phase	Monophasic rectangular wave-form single phase
Pulse width	30 - 300uS	300uS
Max. output current	70mA	100mA
Polarity	Red = plus, Black = minus	Red = plus, Black = minus
Power source	battery powered	battery powered
Batteries	AAA 4ea. Alkaline or Rechargeable	9V 1ea. Alkaline or Rechargeable
Dimensions	141(L) x 60(W) X 18(H) mm	114 x 60 x 31 mm
Weight	115 grams (with batteries)	158 (with batteries)

Performance:

Locking feature	keyboard lock (safety feature)	keyboard lock (safety feature)
Alarm	electrode alarm	electrode alarm
Level Adjustment	Intensity adjustment (by 0.5 mA)	Level Adjustment (adjust by 1 mA)
Treatment Timer	Treatment Timer with auto shut off	Treatment Timer with auto shut off
Auto treat & repeat	automatic setting & repeat of treatment	automatic setting & repeat of treatment

The design of both the applied for device and the predicate device are substantially equivalent to each other in almost every way. The AMD 6605 has basic technological characteristics that are substantially equivalent to the TENS and NMES (Powered Muscle Stimulator) predicate devices. They all have preset output energy levels selectable by depression of a button. All units store and recall the desired treatment as selected by the physician or medical practitioner. All units have biocompatible shrouded cables that comply with the FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables". All of the units are power sourced by battery. All of the devices also deliver the stimulation impulses through biocompatible electrodes that have a contact membrane that is made from an Amgel product (US manufactured) or equivalent materials. The predicate device uses a 9 volt battery and the AMD 6605 uses 4ea. AAA alkaline batteries.

Both devices have two independently controlled channels, with a retangular wave form, a pulse width of 300 uS. The predicate device has a stronger output current (100mA) than the AMD 6605's (70mA). The AMD 6605 gives a muscle contraction that is not quite as intense as the predicate device and is considered an equivalent device in working on relieving pain and muscle re-education ability. We have evaluated both devices side by side matching the specifications and outputs as they relate to the AMD 6605 .

Safety standards met:

Biocompatibility:	ISO 10993-1:1997	Information NOT Available Information NOT Available
Biocompatibility:	ISO 10993-12:2007	Information NOT Available
Biocompatibility:	ISO 10993-10:2002	Information NOT Available
General Safety Requirements:	IEC 60601-1:1988+A1:1991+A2:1995	Information NOT Available
Electromagnetic Compatibility:	IEC 60601-1-2:2001/A1:2004	Information NOT Available
Safety Requirements:	IEC 60601-1-4:2000	Information NOT Available
Declaration of Conformity	IEC 60601-1-6:2004	Information NOT Available

Non-Clinical Data:

Various reports were used in determining the substantial equivalence of the AMD 6605 to the predicate device. Including an EC Test report, A Safety Test report and a Substantial Equivalents Report.

A review of these documents will show that the AMD 6605 is substantially equivalent to the Elpha II 3000 and has passed all required Safety testing. Both devices have similar programs and functionality.

1. Risk Analysis results demonstrate acceptable and mitigated potential hazards.
2. The device will meet the following standards:

IEC 6060 1-1
IEC 6060 1-1-2
IEC 6060 1-1-4:2000
IEC 60601-2-10 Amd.1 (2001-09)
AAMI/ANSI/ISO 10993-12:2007
AAMI/ANSI.ISO 10993-10:2002
AAMI/ANSI/ISO 10993-1:2003(E)

Conclusion:

The device is designed and labeled and verified for performance and safety.
The performance is equivalent to legally marketed predicate devices. Risk Analysis does not demonstrate any design or performance potential hazards that are not adequately mitigated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Advantageous Medical Device, LLC
c/o Jeff D. Rongero
Third Party Reviewer, Senior Project Engineer
Underwriters, Laboratory Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

OCT 23 2009

Re: K092990
Trade Name: AMD 6605 TENS/NMES
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ; IPF
Dated: September 25, 2009
Received: September 28, 2009

Dear Mr. Rongero:

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 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" (21CFR 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

K092990

Indications For Use

510(k) Number (K092990):

Device Name: **AMD 6605**

Indications for Use:

TENS:
• Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain

NMES:
• Relaxation of muscle spasms
• 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

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 IF 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 K092990