AUG 16 2006

510(k) Summary
for the Biowave Deepwave Percutaneous Neuromodulation Pain Therapy System

1. SPONSOR

Biowave Corporation
16 Knight Street
Norwalk, CT 06851

Contact Person: Brad Siff
Telephone: (203) 247-9020

Date Prepared: July 19, 2006

2. DEVICE NAME

Proprietary Name:	Deepwave Percutaneous Neuromodulation Pain Therapy System
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Percutaneous Electrical Nerve Stimulation Devices

3. PREDICATE DEVICES

- Vertis NeuroScience Inc., Percutaneous Neuromodulation Control Unit and Accessories (K022241)
- Biowave Corporation's Deepwave Neuromodulation Pain Therapy Device (K052289)

4. INTENDED USE

The Deepwave Percutaneous Neuromodulation Pain Therapy System is comprised of a percutaneous electrode array and the Deepwave Neuromodulation Pain Therapy Device. The Deepwave Percutaneous Neuromodulation Pain Therapy System is indicated for:

- Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain;

- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

5. DEVICE DESCRIPTION

Biowave Corporation's Deepwave Percutaneous Neuromodulation Pain Therapy System is essentially identical to Biowave's Deepwave Neuromodulation Pain Therapy Device cleared under K052289 except that the proposed device includes a percutaneous electrode array instead of standard surface electrodes.

The percutaneous electrode array (***PEA***) is a sterile, single-use microneedle patch which facilitates the delivery of electrical signals through the skin into tissue. The size of the ***PEA*** patch is 2.5 inches in diameter. In the center of the patch is a 1.5 inch diameter array of 1014 microneedles made from medical grade 316L stainless steel which are 736 microns (0.736 millimeters) in length. When placed onto the skin the ***PEA*** feels like sandpaper or Velcro to the touch. The Feed Pad is a standard electrode that is 2" x 4" or 5" x 8" in size. The Deepwave Percutaneous Neuromodulation device sends a signal from the Feed Pad through the body to the PEA.

The Deepwave Percutaneous Neuromodulation Pain Therapy Device is a battery-powered device intended to provide clinicians with the ability to prescribe PENS therapy. The device measures approximately 7.4 inches wide, 5.6 inches long, and 2.25 inches deep, weighs about 3 pounds, and operates on a 12 volt rechargeable NiMH battery that is enclosed within the unit. The unit will not operate while it is plugged into the wall to recharge the battery. The patient controls the amplitude of the signal with two buttons (a Plus (+) Button and a Minus (-) Button) on the face of the device. An LCD displays the amplitude of the signal in numerical format. Two wires emanate from the unit. One wire is attached to a large disposable electrode pad placed opposite the source of pain ("***Feed Pad***"). The second wire is attached to a smaller microneedle patch called a Percutaneous Electrode Array ("***PEA***") placed directly over the source of the pain (the treatment site).

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Deepwave Percutaneous Neuromodulation Pain Therapy System, the Vertis Percutaneous Neuromodulation Therapy device and the Deepwave Neuromodulation Pain Therapy device are identical in indications in that they are all indicated for the symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute

pain and the symptomatic relief of post-operative pain. Biowave's Deepwave Percutaneous Neuromodulation Pain Therapy System and the Vertis device are PENS devices that use percutaneous electrodes whereas Biowave's Deepwave Neuromodulation Pain Therapy device is a TENS that uses a standard TENS electrode. The use of Biowave's percutaneous electrode array (PEA) does not affect safety or effectiveness since the Biowave PEA penetrates less depth of the skin than the Vertis PEA.

The Basic Unit Characteristics and Output Specifications are similar for the Neuromodulation Pain Therapy and the predicate device according to the requirements of the FDA Guidance Document for Powered Muscle Stimulator 510(k) s, Attachment II, Guidance for Reporting Technological Characteristics. Biowave Corporation's Deepwave Percutaneous Neuromodulation Pain Therapy System and the Vertis PENS device are similar in design and function. Both devices offer percutaneous electrodes, a biphasic waveform and a beat frequency in the range of 100-200 Hz. Both the proposed and predicate devices are software driven PENS units that provide the user with a treatment program for pain reduction.

The conclusion of this technical comparison is that Biowave Corporation's Deepwave Percutaneous Neuromodulation Pain Therapy System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2006

Biowave Corporation
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Culliname, RAC
Staff Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K061166
Trade/Device Name: Deepwave Percutaneous Neuromodulation Pain Therapy System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NHI, GZJ
Dated: July 19, 2006
Received: July 20, 2006

Dear Ms. McNamara-Culliname:

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.

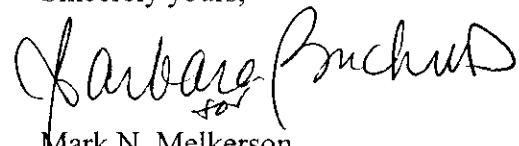
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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):

Device Name:

Indications For Use:

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)

K061166

Indications for Use

510(k) Number (if known):

Device Name: Deepwave Percutaneous Neuromodulation Pain Therapy System

Indications for Use:

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- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

Prescription Use ___X___ 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)

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

510(k) Number K061166