K072123

Special 510(k) Summary
for the Biowave
Homewave Neuromodulation Pain Therapy Device

1. SPONSOR

Biowave Corporation
16 Knight Street
Norwalk, CT 06851

FEB - 1 2008

Contact Person: Brad Siff
Telephone: (203) 855-8610

Date Prepared: January 18, 2008

2. DEVICE NAME

Proprietary Name:	Homewave Neuromodulation Pain Therapy Device
Common/Usual Name:	Electrical Nerve Stimulator
Classification Names:	TENS, Interferential Current Stimulator

3. PREDICATE DEVICES

- Deepwave Neuromodulation Pain Therapy Device, K052289
- Deepwave PENs Neuromodulation Pain Therapy Device, K061166
- Johari Digital Healthcare Ltd. K060246

4. INTENDED USE

The Homewave Neuromodulation Pain Therapy Device is indicated for:

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

5. DEVICE DESCRIPTION

The purpose of this Special 510(k) is to obtain clearance to market a modified version of the Deepwave Neuromodulation Pain Therapy Device (K052289) and the Deepwave PENS Neuromodulation Pain Therapy Device (K061166). The parent Biowave Deepwave Neuromodulation Pain Therapy Device (K052289) and Biowave Deepwave PENS Neuromodulation Pain Therapy Device (K061166) have indications for use that are the same as TENS and interferential stimulation devices.

Biowave has made some minor modifications to the Deepwave Neuromodulation Device resulting in a safer and easier-to-use device for the end-user (called the Homewave device). The minor modifications are as the follows:

- Homewave has a smaller power supply (lithium ion polymer rechargeable battery) that will last approximately 3 hours vs. 8 hours for Deepwave)
- Homewave includes a custom connector at the end of the electrode that houses an electronic integrated circuit ("chip"). The Homewave device checks the electronic chip when the electrode is attached to the leadwires, and the leadwires to the device. The electronic chip limits the use of the pad to 5 twenty-minute treatments or 100 minutes of total use.
- Treatment time is fixed for Homewave at 20 minutes vs. adjustable between 5-60 minutes for Deepwave.

The modified Homewave Neuromodulation Device has the identical intended use, indications and functionality as the original Deepwave Neuromodulation Device described in K052289 and the Deepwave PENS Neuromodulation Pain Therapy Device described in K061166.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Biowave Corporation's Homewave and Deepwave devices are similar in design and function. Both devices offer a dual sinusoidal signal with a frequency difference of 122 Hz. Both the proposed and predicate devices are software controlled TENS units that provide the user with pain reduction. The conclusion of this technical comparison is that Biowave's Homewave Device is substantially equivalent to the predicate devices for the indications specified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2008

Biowave Corporation
% Mr. Brad Siff
16 Knight Street
Norwalk, CT 06851

Re: K072123
Trade/Device Name: Homewave Neuromodulation Pain Therapy Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: January 18, 2008
Received: January 22, 2008

Dear Mr. Siff:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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: Homewave Neuromodulation Pain Therapy Device

The Homewave Neuromodulation Pain Therapy Device is indicated for:

- Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain
- Symptomatic relief of acute 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 K072123