DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Biowave Corporation
Mr. Bradford Siff
Founder and Chief Technology Officer
16 Knight St.
Norwalk, Connecticut 06851

September 25, 2015

Re: K152437
Trade/Device Name: BiowaveHOME 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: GZJ
Dated: August 27, 2015
Received: August 28, 2015

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. 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 contact the Division of Industry and Consumer Education 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. 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/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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152437

Device Name
BiowaveHOME Neuromodulation Pain Therapy System

Indications for Use *(Describe)*
The BiowaveHOME 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary

for Biowave Corporation's

BiowaveHOME Neuromodulation Pain Therapy Device

1. Sponsor

Biowave Corporation
16 Knight Street
Norwalk, CT 06851

Contact Person: Brad Siff
Telephone: 1-877-246-9283 ext 6 or 203-247-9020

Date Prepared: August 12, 2015

2. Device Name

Proprietary Name: BiowaveHOME Neuromodulation Pain Therapy Device

Common/Usual Name: Electrical Nerve Stimulator

Classification Names: Transcutaneous Electrical Nerve Stimulator
K152437 - Product Code: GZJ

3. Predicate Devices

Homewave Neuromodulation Pain Therapy Device, K072123

Deepwave (BiowavePRO) Neuromodulation Pain Therapy Device, K053389

Deepwave Percutaneous (BiowavePENS) Neuromodulation Pain Therapy System, K053389

4. Intended Use

The BiowaveHOME 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 Homewave Neuromodulation Pain Therapy Device (K072123). Biowave Corporation's parent Homewave Neuromodulation Pain Therapy Device (K072123) is a TENS type device with a single optimized operational mode for the treatment of pain.

Biowave has made some minor modifications to the Homewave Neuromodulation Device resulting in the proposed BiowaveHOME device. The minor modifications involve the following:

- BiowaveHOME has a newer more advanced power supply, two lithium iron phosphate batteries, that will last longer between charges and can sustain approximately 3 times the number of charge/discharge cycles versus Homewave's three lithium ion batteries. Lithium iron phosphate rechargeable batteries are also safer than lithium ion with respect to overheating and over or under charging issues.

- BiowaveHOME utilizes a larger custom LCD display with larger characters making it much easier to read the intensity and count down timer and other information as compared to Homewave.

- BiowaveHOME has a PAUSE button added to the face of the device giving the patient an obvious choice to pause or stop the treatment if necessary.

- BiowaveHOME has a smaller more ergonomic form factor making it easier to hold and move about as compared to Homewave.

The modified BiowaveHOME Neuromodulation Pain Therapy Device has the identical intended use, indications and functionality as the original Homewave Neuromodulation Pain Therapy Device described in K072123.

6. Basis for Substantial Equivalence

Biowave Corporation's BiowaveHOME and Homewave Neuromodulation Pain Therapy Devices are similar in design and function. Both devices deliver and target a summation of two alternating current high frequency sinusoidal waveforms into deep tissue within the body from which a low frequency electric field forms encompassing the source of pain.

Both the proposed and parent devices are software driven TENS type units that provide the user with a single optimized treatment program for pain reduction.

The conclusion of this technical comparison is that Biowave Corporation's BiowaveHOME Neuromodulation Pain Therapy Device is substantially equivalent to the parent devices for the indications specified.