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,

Barbara Buchwald for

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:

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.

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

Product Classification Database

Device	Nerve,Stimulator,Electrical,Percutaneous (Pens) For Pain Relief
Regulation Description	Transcutaneous electrical nerve stimulator for pain relief.
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	NHI
Submission Type	510(k)
Regulation Number	882.5890
Device Class	2
GMP Exempt?	No
Third Party Review	

- Eligible for *Accredited Persons Expansion Pilot Program*

Accredited Persons

- California Department Of Health Services
- Citech
- Entela, Inc.
- Intertek Testing Services
- Kema Quality B.V.
- Regulatory Technology Services, Llc
- Tuv America, Inc.
- Tuv Rheinland Of North America, Inc.
- Underwriters Laboratories, Inc.

Database Updated 1/09/2007

Product Classification Database

Device	Stimulator, Nerve, Transcutaneous, For Pain Relief
Regulation Description	Transcutaneous electrical nerve stimulator for pain relief.
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	GZJ
Submission Type	510(k)
Regulation Number	882.5890
Device Class	2
GMP Exempt?	No
Third Party Review	

- Eligible for *Mutual Recognition Agreement Program*
- Eligible for *Accredited Persons Program*

Accredited Persons

- California Department Of Health Services
- Center For Measurement Standards Of Industrial
- Cheiroon Bv
- Citech
- Entela, Inc.
- Intertek Testing Services
- Kema Quality B.V.
- Regulatory Technology Services, Llc
- Tuv America, Inc.
- Tuv Rheinland Of North America, Inc.
- Underwriters Laboratories, Inc.

Database Updated 1/09/2007