



AUG 20 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Rashelle Preston  
Director of Special Projects  
Body Clock Health Care Ltd  
108 George Lane  
South Woodford  
London  
E18 1AD England

Re: K041359  
Trade/Device Name: Body Clock Stimplus and Body Clock Stimplus Pro  
Regulation Number: 21 CFR 882.5890  
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief  
Regulatory Class: II  
Product Code: GZJ  
Dated: May 18, 2004  
Received: May 21, 2004

Dear Ms. Preston:

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.

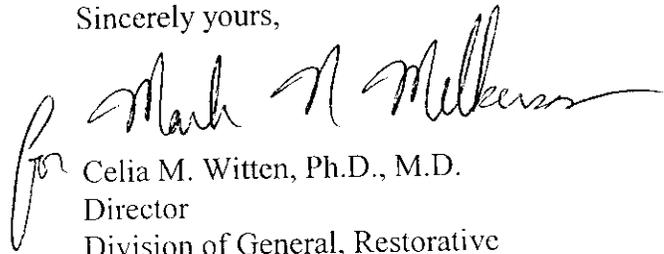
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Milken". The signature is written in a cursive style and is positioned to the left of the typed name and title.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

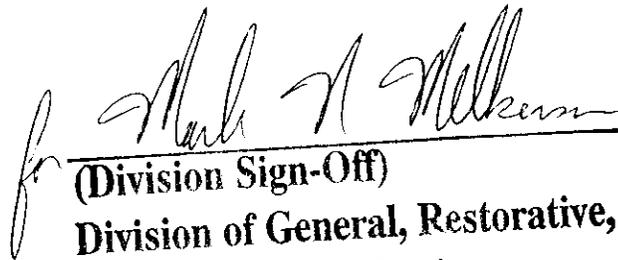
**8 Statement of Indications For Use**

510 (k) Number (if known): \_\_\_\_\_

Device Name/s:       Body Clock Stimplus Pro  
                          Body Clock Stimplus

**Indications For Use:**

The Body Clock Stimplus Pro and Body Clock Stimplus are used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number           K041359          

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 \_\_\_\_\_

Prescription Use       X  
(Per 21 CFR 801.109)