APR 5 - 2007

K062784

510(k) Summary of Safety and Effectiveness (as required by 21 CFR § 807.92)

Date Prepared	March 22, 2007
Submitter	Neuro-Fitness, LLC 33631 S.E. Redmond / Fall City Rd. #2, Fall City, WA 98024 Phone: 425-222-0830, Fax: 425-222-7413 Contact: Michael Stevens
Device Names	Trade Name: *CES Ultra™* Common Name: *Cranial Electrotherapy Stimulator (CES)* Classification Name: *Stimulator, Cranial, Electrotherapy*, a preamendment Class III device per 21 CFR § 882.5800 (JXK)
Predicate Devices	NF-1 Mindpeace CES, K895175, Neuro-Fitness, LLC HP-1 Healthpax CES, K883812, Healthdirections, Inc.
Device Description and Summary of Technological Characteristics	The *CES Ultra* is a device designed to deliver therapeutic electrical stimulation for cranial electrotherapy stimulation (CES) applications. The stimulator is powered by a standard 9-volt alkaline battery and delivers a single channel of low-level, constant current electrical stimulation to electrodes connected to the patient's skin via conductive lead wires. Stimulation current is applied to the patient via either standard self-adhering conductive electrodes placed on the head or conductive clip-type electrodes attached to the patient's ear lobes. The stimulator's user controls include: a rotary stimulation amplitude control which allows user adjustment of stimulation current and includes an integral power on/off switch; and a pushbutton timer selector switch which allows user selection of either continuous stimulation or timed stimulation sessions with automatic stimulation shut-off.
Indications for Use	The *CES Ultra* is indicated for the treatment of insomnia, depression or anxiety.
Substantial Equivalence	The *CES Ultra* was originally determined by FDA to be substantially equivalent to legally marketed CES devices under K895175. The *CES Ultra* utilizes stimulation parameters (i.e., frequency, pulse width and amplitude) that are well within the established range of such parameters that are generally accepted as safe and effective for CES.
Device Testing	Neither nonclinical nor clinical testing was required to demonstrate the substantial equivalence of the *CES Ultra* to the designated predicate devices. However, standard engineering bench testing has been performed where appropriate to verify conformance to specifications.

Special Controls

No Special Controls, including performance standards under section 514 of the Act, have been established for CES. However, the conductive lead wires to be used with the *CES Ultra* are subject to, and comply with, the requirements of 21 CFR Part 898, *Performance Standard for Electrode Lead Wires and Patient Cables.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 - 2007

Neuro-Fitness, LLC
% Mr. Michael Stevens
Vice President
P.O. Box 1031
Snoqualmie, Washington 98065

Re: K062284
Trade/Device Name: *CES Ultra™ Stimulator*
Regulation Number: 21 CFR 882.5800
Regulation Name: Cranial electrotherapy stimulator
Regulatory Class: Class III
Product Code: JXK
Dated: March 5, 2007
Received: March 12, 2007

Dear Mr. Stevens:

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 Statement

510(k) Number: K062284

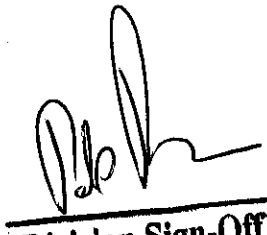
Device Name: *CES Ultra*™ Stimulator

Indications for Use: The *CES Ultra*™ is indicated for the treatment of insomnia, depression, or anxiety.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K062284