K080219

510(k) SUMMARY

NESS, Ltd.'s NESS L300

510(k) Summary:
NESS L300

Company Name:
NESS--Neuromuscular Electrical Stimulation Systems, Ltd.

Contact Person:
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R&D and Clinical Manager

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Authorized US Agent:
Bioness, Inc.
25103 Rye Canyon Loop
Valencia, CA 91355

Date prepared:
January 29, 2008

Trade Name:
NESS L300

Classification name:
External functional neuromuscular stimulator

Class: II

Panel identification:
Neurological devices

Product code:
GZI and IPF

Regulation number:
882.5810 External functional neuromuscular stimulator
890.5850 Powered Muscle Stimulator

Predicate Devices:

Neuromuscular Electrical Stimulation Systems, Ltd.'s NESS L300 (K053468)

Purpose of the Special 510(k) notice.

The NESS L300 is a modification to the NESS L300 (K053468).

Device description:

This neuroprosthesis device consists of a RF foot sensor (Intelli-sense gait sensor), RF control unit (waist mounted / neck strap / in pocket), and a below the knee orthosis containing electrodes and a RF controlled stimulation unit (RF stim unit).

The Intelli-gait sensor detects "heel off" and "heel contact" events during gait and transmits signals to the RF stim unit. Accordingly, the RF stim unit initiates and pauses the stimulation, activating the foot dorsiflexors to ensure proper foot clearance during the swing phase and proper foot placement during the stance phase.

The NESS L300 comprises of 4 main parts:

1. A lower leg orthosis with integrated RF stim unit and electrodes, RF communication, and rechargeable battery.
2. A waist mounted (or in-pocket) Control Unit (CU), including a PDA (clinician programmer) interface, RF communication, and AAA rechargeable battery.
3. Intelli-sense gait sensor with RF communication and non-rechargeable coin battery.
4. Clinician Programmer - Handheld computer (PDA)

Indications for Use:

The NESS L300 is intended to provide ankle dorsiflexion in individuals with drop foot following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot; thus, it may improve the individual's gait. The NESS L300 may also facilitate muscle re-education, prevent/retard disused atrophy, maintain or increase joint range of motion and increase local blood flow.

Substantial Equivalence:

The modified NESS L300 has the same intended use and similar indications, principles of operation, and technological characteristics as the original, cleared NESS L300. The minor differences in the embedded software, the Intelli-Gait (PDA) software, the hardware, and the accessories do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified NESS L300 is as safe and effective as the predicate device. Thus, the NESS L300 is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Neuromuscular Electrical Stimulation Systems
% Dr. Evan Rosenfeld
Bioness Incorporated
25103 Rye Canyon Loop
Valencia, CA 91355

Re: K080219
Trade/Device Name: Modification to NESS L300
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: January 29, 2008
Received: January 29, 2008

Dear Dr. Rosenfeld:

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 Statement

510(k) Number (if known): K080219

Device Name: NESS L300

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Prescription Use __X___ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080219