

APR 29 2011

**510(k) Summary****Bioness Neuromodulation Ltd., a Bioness Inc. Company.****NESS L300 Plus system****510(k) Summary:**

NESS L300 Plus System

**Company name:**

Bioness Neuromodulation Ltd., a Bioness Inc. company.

**Contact person:**

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Bioness Neuromodulation Ltd.

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25103 Rye Canyon Loop / Valencia, CA 91355 / U.S.A

Bioness Inc.

**Application Correspondent:**

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Bioness, Inc.  
25103 Rye Canyon Loop  
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**Date prepared:**

November 12, 2010

**Trade Name:**

NESS L300 Plus System

**Classification name:**

External functional neuromuscular stimulator

**Class: II****Panel Identification:**

Neurology

**Product code:**

GZI and IPF

**Regulation number:**

882.5810 External functional neuromuscular stimulators

890.5850 Powered muscle stimulators

**Predicate devices:**

- 1) Company: N.E.S.S (Neuromuscular Electrical Stimulation Systems) Ltd.  
Device: NESS L300 (K080219)
- 2) Company: N.E.S.S (Neuromuscular Electrical Stimulation Systems) Ltd.  
Device: NESS system (K022776)

**Purpose of the traditional 510(k) notice:**

The NESS L300 Plus is a new device based on the NESS L300 and on the NESS system.

**Device description:**

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness, following an upper motor neuron injury or disease. The NESS L300 Plus System is a combination of its two predicate devices of its two predicate devices, the NESS L300 (K080219) and the NESS System (K022776).

The NESS L300 Plus System consists of:

- A Control Unit that allows simple operation while displaying real time information regarding the system's status.
- Two Functional Stimulation Cuffs (L300 and Thigh, figures 11-2, 11-3 respectively), that include two surface electrodes and an integrated configurable Radio Frequency Stimulation unit each.
- A Gait Sensor, which uses a dynamic gait tracking algorithm to detect heel events and wirelessly synchronizes stimulation.

- A Clinician's Programming System with software, which is used for system programming by a trained clinician during configuration of the system for optimal fitting to the patient.
- A L300 Tester. The L300 Tester is utilized for checking the RFSs and FSCs for functionality.
- A power supply with a 3-way splitter cable to charge the Control Unit and both Radio Frequency Stimulation units.

**Indications for use:**

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness, following an upper motor neuron injury or disease. During gait, the L300 Plus System electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot and knee flexion or extension, thus it may improve the individual's gait. The L300 Plus System may also:

- Facilitate Muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

**Substantial Equivalence:**

The Ness L300 Plus is a combination of the NESS L300 (K080219) and the thigh module from the NESS system (K022776).

The primary predicate device is the NESS L300 which is included in the NESS L300 Plus system almost in its entirety. The NESS L300 Plus incorporates all of the NESS L300 components excluding the control unit which is replaced with a new control unit for the L300 Plus. The NESS L300 Plus also incorporates a version of the thigh module from the NESS system, adapted to the L300 Plus system.

The NESS L300 Plus shares the intended use, technology and stimulation methods and main components with its predicate devices and in particular with the NESS L300.

**Conclusion:**

Bioness Neuromodulation believes that the NESS L300 Plus is substantially equivalent to the NESS L300 (K080219) and the NESS (K022776) predicate systems without raising any new safety and effectiveness concerns.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Bioness Inc.  
% Ms. Adele Shoustal  
Director, Regulatory and Clinical Affairs  
25103 Rye Canyon Loop  
Valencia, CA 91355

APR 29 2011

Re: K103343  
Trade Name: NESS L300 Plus System  
Regulation Number: 21 CFR 882.5810  
Regulation Name: External functional neuromuscular stimulator  
Regulatory Class: Class II  
Product Code: GZI, IPF  
Dated: April 22, 2011  
Received: April 25, 2011

Dear Ms. Shoustal:

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 go to

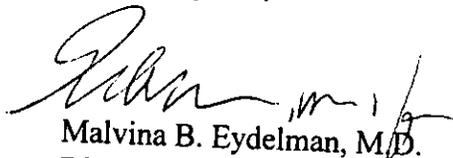
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance.

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 Small Manufacturers, International and Consumer Assistance 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,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

K103343



Section 4  
Indications for Use Statement

**Indications for Use**

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

Device Name: NESS L300 Plus System

Indications for Use:

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness, following an upper motor neuron injury or disease. During gait, the L300 Plus System electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot and knee flexion or extension, thus it may improve the individual's gait. The L300 Plus System may also:

- Facilitate Muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE):

(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number  K103343