K122784

510(k) Summary

DEC 2 7 2012

510(k) Summary	L300® System
Company name	Bioness Inc.
Contact persons	

Kim Tompkins, VP, Regulatory and Clinical Affairs

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Date prepared	October 30, 2012
Trade Name	L300® Foot Drop System or NESS L300 Foot Drop System
Classification name	External functional neuromuscular stimulator
Classification	II
Panel Identification	Neurology
Product code(s)	GZI and IPF
Regulation numbers	882.5810 External functional neuromuscular stimulators 890.5850 Powered muscle stimulators
Purpose of the 510(k)	To modify the indications for use

Predicate devices

1. NESS (Neuromuscular Electrical Stimulation Systems) Ltd. (currently known as Bioness Neuromodulation Ltd., a Bioness Inc. Company) NESS L300 System (K120853, SE 4.20.2012)
2. Innovative Neurotronics Walkaide System (K052329, SE 9.21.2005)

Device description

The L300 Foot Drop System consists of

- Functional Stimulation (FS) Cuff with a Radio Frequency (RF) Stimulation Unit
- Control Unit
- Intelli-Sense Gait Sensor

Indications for use

The NESS L300 Foot Drop System is intended to provide ankle dorsiflexion in individuals (adults and pediatrics) who have foot drop 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. The NESS L300 may improve gait, facilitate muscle re-education, prevent or retard disuse atrophy, maintain or increase joint range of motion, and increase local blood flow.

Substantial Equivalence

The L300 System subject device is identical to the L300 System (K120853). It is similar to the Walkaide System (K052329) currently marketed for pediatric use. Electrical stimulation is well documented in the literature and confirmed in clinical performance as a safe and effective treatment for functional electrical stimulation.

Conclusion

The L300 System modified indications for use is substantially equivalent to the cleared L300 System and the cleared Walkaide System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Bioness, Inc.
% Ms. Kim Tompkins
VP of Regulatory and Clinical Affairs
25103 Rye Canyon Loop
Valencia, CA 91355

DEC 2 7 2012

Re: K122784
Trade Name: NESS L300® System
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator.
Regulatory Class: Class II
Product Code: GZI & IPF
Dated: November 2, 2012
Received: November 5, 2012

Dear Ms. Tompkins:

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,

Tina Kiang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Device
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122784

Device Name: NESS L300® System

Indications for Use:

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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 K122784