



Food and Drug Administration
10903 New Hampshire Avenue
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July 23, 2015

Niveus Medical, Inc.
c/o Cindy Domecus
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, CA, 94010

Re: K150742

Trade/Device Name: Muscle Stimulation System 110
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: June 19, 2015
Received: June 26, 2015

Dear Ms. Domecus,

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Carlos L. Pena 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150742

Device Name

Muscle Stimulation System 110

Indications for Use (Describe)

The Niveus Medical Muscle Stimulation System 110 is indicated for:

- 1) Maintaining or increasing range of motion of the knee joint
- 2) Prevention or retardation of disuse atrophy in the quadriceps
- 3) Muscle re-education of the quadriceps
- 4) Relaxation of muscle spasms
- 5) Increasing local blood circulation

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

510(k) Owner:

Niveus Medical, Inc.
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Mountain View, CA 94043
650-336-7922 (phone)

Contact Person:

Cindy Domecus, R.A.C. (US &EU)
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Date Prepared:
July 23, 2015

II. DEVICE

| | |
|-----------------------|---|
| Name of Device: | Muscle Stimulation System 110 |
| Common or Usual Name: | Powered Muscle Stimulator |
| Classification Name: | Powered Muscle Stimulator (21 CFR 890.5850) |
| Regulatory Class: | II |
| Product Code: | IPF |

III. PREDICATE DEVICE

The predicate device is the Niveus Medical Muscle Stimulation System 110 cleared under K123642.

The predicate device has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Muscle Stimulation System 110 is a portable, externally-powered device which provides electrical stimulation to the quadriceps using constant current pulses. Pulses are delivered via six independently controlled stimulation channels (3 per leg) and are provided to the patient via electrodes integrated into soft Stimulation

Array Pads. An Interconnect Cable allows for communication between the System Controller and Stimulation Array Pads.

The major components of the system consist of a Controller, an Interconnect Cable, a pair of disposable Stimulation Array Pads configured for application to the quadriceps of a patient, a Power Cord, and Instructions for Use. An optional accessory to the system is the Niveus Medical StayCool FlexPaks.

V. INDICATIONS FOR USE

The Niveus Medical Muscle Stimulation System 110 is indicated for:

- 1) Maintaining or increasing range of motion of the knee joint
- 2) Prevention or retardation of disuse atrophy in the quadriceps
- 3) Muscle re-education of the quadriceps
- 4) Relaxation of muscle spasms
- 5) Increasing local blood circulation

The indications for use are unchanged from the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device represents minor modifications to the predicate device, as follows:

- Update user interface to reflect user preferences
- Minor changes to allow for improved mounting of touchscreen
- A non-functional portion of the bandage material near the Stimulation Array Pad's center is separated from rest of pad such that it remains on release liner during application, leaving a region of uncovered skin in treatment region
- Extend expiration date to 18 months
- An instructional label has been added to the Interconnect Cable connector as an indicator for the top side of the connector

VII. PERFORMANCE DATA

The modification to the user interface was evaluated through software verification testing. The change to the Stimulation Array Pads was evaluated through simulated use testing. The shelf-life extension was supported by real-time aging data.

VIII. CONCLUSION

The bench performance data provided in support of the 510(k) confirm that the subject device is as safe and effective and substantially equivalent to the predicate device.