



April 23, 2021

Neuroolutions, Inc.
% Michael Billig
Chief Executive Officer
Experien Group, LLC
224 Airport Parkway
Suite 250
San Jose, California 95110

Re: DEN200046

Trade/Device Name: Neuroolutions IpsiHand Upper Extremity Rehabilitation System
Regulation Number: 21 CFR 890.5420
Regulation Name: Electroencephalography (EEG)-driven upper extremity powered exerciser
Regulatory Class: Class II
Product Code: QOL
Dated: July 22, 2020
Received: July 23, 2020

Dear Michael Billig:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Neuroolutions IpsiHand Upper Extremity Rehabilitation System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Neuroolutions IpsiHand Upper Extremity Rehabilitation System is indicated for use in chronic stroke patients (≥ 6 months post-stroke) age 18 or older undergoing stroke rehabilitation, to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremity.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Neuroolutions IpsiHand Upper Extremity Rehabilitation System, and substantially equivalent devices of this generic type, into Class II under the generic name electroencephalography (EEG)-driven upper extremity powered exerciser.

FDA identifies this generic type of device as:

Electroencephalography (EEG)-driven upper extremity powered exerciser. An EEG-driven upper extremity powered exerciser is a non-invasive prescription device intended for rehabilitation by driving movement or exercise of an impaired upper extremity in response to the detection of purpose oriented electrical activity produced by the patient's brain.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On July 23, 2020, FDA received your De Novo requesting classification of the Neuroolutions IpsiHand Upper Extremity Rehabilitation System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Neuroolutions IpsiHand Upper Extremity Rehabilitation System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Neuroolutions IpsiHand Upper Extremity Rehabilitation System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Device provides ineffective treatment, leading to worsening condition	Clinical performance testing Software verification, validation, and hazard analysis Wireless compatibility testing
Unintended motion leading to injury	Software verification, validation, and hazard analysis
Thermal injury including burns and shock	Electromagnetic compatibility (EMC) testing Electrical safety testing Battery safety testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Cross contamination, leading to infection or adverse tissue reaction	Reprocessing validation Labeling
Pain or discomfort including: <ul style="list-style-type: none"> • Headache • Fatigue • Skin redness 	Labeling Clinical performance testing

In combination with the general controls of the FD&C Act, the electroencephalography (EEG)-driven upper extremity powered exerciser is subject to the following special controls:

- (1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must capture any adverse events observed during clinical use and must demonstrate that the EEG signal can be translated into intended motion.
- (2) Software verification, validation, and hazard analysis must be performed.
- (3) Performance data must demonstrate the electromagnetic compatibility, electrical safety, battery safety, and wireless compatibility of the device.
- (4) The device components that contact the patient must be demonstrated to be biocompatible.
- (5) Performance data must validate the reprocessing instructions for the reusable components of the device.
- (6) Labeling must include:
 - (i) Instructions on fitting the device to the patient;
 - (ii) Information on how the device operates and the typical sensations experienced during treatment; and
 - (iii) Reprocessing instructions.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the electroencephalography (EEG)-driven powered exerciser they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combo-products/guidance-regulatory-information/postmarketing-safety-reporting-combo-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531 - 542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation -emitting products, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Heather Dean, PhD at 240-402-9874.

Sincerely,

Christopher Loftus, M.D.
Acting Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health