



May 18, 2022

NeuroMetrix, Inc.  
% John Doucet  
Senior Director  
MCRA  
803 7th Street, NW, 3rd Floor  
Washington, District of Columbia 20001

Re: DEN210046

Trade/Device Name: Quell-FM

Regulation Number: 21 CFR 882.5888

Regulation Name: Transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms

Regulatory Class: Class II

Product Code: QSQ

Dated: October 4, 2021

Received: October 5, 2021

Dear John Doucet:

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 Quell-FM, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Quell-FM is a transcutaneous electrical nerve stimulation (TENS) device indicated as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. The Quell-FM may be used during sleep. The Quell-FM is labeled for use only with compatible NeuroMetrix electrodes.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Quell-FM, and substantially equivalent devices of this generic type, into Class II under the generic name transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms.

FDA identifies this generic type of device as:

**Transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms.** A transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms is a prescription device that transcutaneously stimulates a patient's sensory nerves through electrodes placed on the skin.

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 October 5, 2021, FDA received your De Novo requesting classification of the Quell-FM. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Quell-FM 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 Quell-FM 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:

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Adverse tissue reaction	Biocompatibility evaluation
Skin discomfort, burns, electrical shock, or pain at stimulation site	Electromagnetic compatibility testing Electrical, mechanical, and thermal safety testing Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Device failure due to interference with other devices	Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Labeling
Delayed or ineffective treatment due to user error	Labeling

In combination with the general controls of the FD&C Act, the transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms is subject to the following special controls:

- (1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must include:
  - (i) Characterization of the electrical stimulation parameters, including the following: waveforms; output modes; maximum output voltage and maximum output current (at 500 $\Omega$ , 2k $\Omega$ , and 10k $\Omega$  loads); pulse duration; frequency; net charge per pulse; maximum phase charge, maximum current density, maximum average current, and maximum average power density (at 500 $\Omega$ );
  - (ii) Characterization of the impedance monitoring system; and

- (iii) Characterization of electrode performance, including the electrical performance, adhesive integrity, shelf life, reusability, and current distribution of the electrode surface area.
- (2) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (3) Performance testing must demonstrate electrical, thermal, and mechanical safety along with electromagnetic compatibility (EMC) of the device in the intended use environment.
- (4) Software verification, validation, and hazard analysis must be performed.
- (5) Labeling must include the following:
  - (i) Recommended treatment regimes, including but not limited to, frequency and duration of use, application site(s), and typical sensations experienced during treatment.
  - (ii) A shelf life for the electrode and reuse information.
  - (iii) Summaries of the electrical stimulation parameters and device technical parameters (including any wireless specifications).
  - (iv) Instructions on how to correctly use and maintain the device, including all user-interface components.

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](mailto: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 transcutaneous electrical nerve stimulator to treat fibromyalgia symptoms 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-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](mailto: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 Phoebe Xu at (301) 796-2068.

Sincerely,

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