November 13, 2024

ClearPoint Neuro, Inc.
Brennan Sullivan
Regulatory Affairs
120 S. Sierra Avenue, Suite 100
Solana Beach, California 92075

Re: DEN240023
Trade/Device Name: SmartFlow Neuro Cannula
Regulation Number: 21 CFR 882.4110
Regulation Name: Brain intraparenchymal infusion cannula
Regulatory Class: Class II
Product Code: SDG
Dated: May 20, 2024
Received: May 22, 2024

Dear Brennan Sullivan:

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 SmartFlow Neuro Cannula, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The SmartFlow Neuro Cannula, when used with compatible stereotaxic and therapeutic delivery devices, is indicated for intraputaminal administration of eladocagene exuparvovec-tneq for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SmartFlow Neuro Cannula, and substantially equivalent devices of this generic type, into Class II under the generic name brain intraparenchymal infusion cannula.

FDA identifies this generic type of device as:

> **Brain intraparenchymal infusion cannula**. A brain intraparenchymal infusion cannula is a non-powered, hollow tube-like device with a rigid component for stereotaxic-aided temporary placement in brain parenchyma tissue to deliver a therapy.

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 May 22, 2024, FDA received your De Novo requesting classification of the SmartFlow Neuro Cannula. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SmartFlow Neuro Cannula 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 SmartFlow Neuro Cannula 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:

Risks to Health	**Mitigation Measures**
Product failure leading to: • Inability to deliver the therapy or incorrect location of the therapy administration • Inaccurate dosing of the therapy • Disease progression	In vivo performance testing Non-clinical performance testing Labeling
Adverse tissue reaction	In vivo performance testing Biocompatibility evaluation
Tissue injury resulting from • Device breakage • Use error	In vivo performance testing Non-clinical performance testing Human factors/usability testing Labeling
Infection	Sterilization validation Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the brain intraparenchymal infusion cannula is subject to the following special controls:

(1) In vivo performance testing must demonstrate that the device performs as intended to deliver the intended dosage of the therapy and evaluate all adverse effects, including adverse tissue reaction and tissue injury.

(2) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:
   (i) A characterization of the therapy distribution profile in the intended brain parenchyma location, including infusate reflux and dose accuracy;
   (ii) Device compatibility with the therapy or analog, including:
      (A) Leachables characterization of the device;
      (B) Particulate testing of the device;
      (C) Characterization of therapy or analog adsorption and aggregation by the device;
      (D) Therapy potency and quality testing; and
      (E) Functional compatibility with other devices intended to be used during the procedure;
   (iii) A characterization of the brain intraparenchymal target placement accuracy in a clinically-relevant phantom compared to a pre-procedure plan; and
   (iv) Mechanical testing:
      (A) Tensile strength;
      (B) Compressive strength;
      (C) Maximum infusion pressure (burst); and
      (D) Leakage.

(3) Human factors/usability testing must demonstrate that the intended user(s) in the intended use environment can correctly and safely use the device in a clinically-relevant workflow following the instructions for use.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must demonstrate the sterility of all patient-contacting components of the device.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(7) Labeling must include:
   (i) Detailed description of the device technical parameters, including physical dimensions and priming volume; and
   (ii) A shelf life.

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 brain intraparenchymal infusion cannula 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).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Adam D. Pierce, Ph.D. at 240-402-6128.

Sincerely,

David P. Mc Mullen -S Date: 2024.11.13 17:12:20 -05'00'

David P. McMullen, M.D.
Director
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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