August 26, 2022

Vibrant Ltd.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, PA 19103

Re: DEN210052
Trade/Device Name: Vibrant System
Regulation Number: 21 CFR 876.5940
Regulation Name: Orally ingested transient device for constipation
Regulatory Class: Class II
Product Code: QTN
Dated: November 30, 2021
Received: November 30, 2021

Dear Janice Hogan:

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 Vibrant System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Vibrant System is an orally administered Capsule that is indicated for the treatment of adults with chronic idiopathic constipation who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Vibrant System, and substantially equivalent devices of this generic type, into Class II under the generic name orally ingested transient device for constipation.

FDA identifies this generic type of device as:

Orally ingested transient device for constipation. An orally ingested transient device for constipation is an electric swallowable capsule that naturally passes through the gastrointestinal tract for the treatment of constipation.

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 November 30, 2021, FDA received your De Novo requesting classification of the Vibrant System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Vibrant 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 Vibrant 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:

Identified Risks to Health	**Mitigation Measures**
Infection	Bioburden testing Labeling Shelf life testing
Adverse tissue reaction	Biocompatibility evaluation
Device malfunction leading to injury	Electrical safety testing Software validation, verification, and hazard analysis Non-clinical performance testing Labeling Shelf life testing
Interference with other devices	Electromagnetic compatibility testing
Failure to excrete capsule	Clinical data Labeling
Device related adverse events including: • Choking • Abdominal pain • Abdominal distension • Abdominal discomfort • Vomiting • Nausea • Proctalgia • Diarrhea	Clinical data Non-clinical performance testing Labeling
Device ineffective leading to constipation and effects of delayed treatment	Clinical data Labeling

In combination with the general controls of the FD&C Act, the orally ingested transient device for constipation is subject to the following special controls:

(1) Clinical data must demonstrate the device performs as intended and evaluate the following:
  (i) Treatment of constipation; and
  (ii) All adverse events.

(2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
  (i) Dimensional testing must verify device dimensions;
  (ii) Performance bench testing must verify functional aspects of the device design;
  (iii) Leak testing must verify device integrity under worst case clinical conditions;
  (iv) Bite testing must demonstrate that the device can withstand bite forces;
  (v) pH resistance testing must evaluate integrity of the capsule when exposed to a physiological relevant range of pH values; and
  (vi) Bioburden testing must demonstrate the device does not pose an infection risk throughout the labeled shelf life.

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

(4) Performance data must support the shelf life of the device by demonstrating continued package integrity and device functionality over the labeled shelf life.

(5) Software validation, verification, and hazard analysis must be performed.

(6) Electrical safety and electromagnetic compatibility (EMC) testing must be performed for any electrical components of the device.

(7) Labeling for the device must include:
  (i) A summary of clinical data for the device, including a discussion of adverse events and clinical benefit; 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 orally ingested transient device for constipation 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) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Joseph Nielsen at 301-796-6244 or josph.nielsen@fda.hhs.gov.

Sincerely,

Joyce M. Whang -S

for
Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health