January 13, 2023

Vibrant Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street
Suite 2300
Philadelphia, PA 19103

Re: K223031
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: October 24, 2022
Received: October 24, 2022

Dear Janice Hogan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Je An -S

Je Hi An, PhD
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement on last page

510(k) Number *(if known)*

K223031

Device Name

Vibrant System

Indications for Use *(Describe)*

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.

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
Vibrant System (K223031)

Submitter

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Phone: +972.46.662379
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Contact Person: Lior Ben Tsur
Date Prepared: January 9, 2023

Trade Name: Vibrant System

Classification Name: Orally Ingested Transient Device For Constipation, 21 CFR 876.5940

Regulatory Class: II

Product Code: QTN

Predicate Device: Vibrant System (DEN210052)

Device Description

The Vibrant System is designed to mechanically induce peristaltic activity in the colon, thus aiding in relieving constipated patients. Constipation relief is achieved by the Capsule's stimulation in the colon, consequently inducing peristaltic activity which promotes transit and facilitates defecation. The stimulation protocol is designed to activate at specific times during the day (i.e., afternoon and evening).

The Vibrant System is comprised of two components: a reusable Pod and a single use capsule. The Capsule is expelled from the body during the patient's bowel movements.

Intended Use/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.

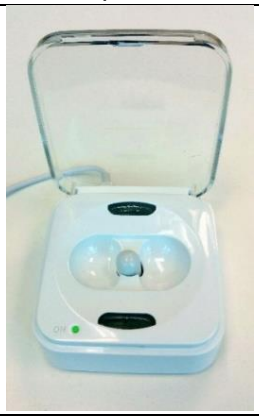
Summary of Technological Characteristics

The following changes were made:

- Addition of cellular network communication that connects through GSM to Vibrant cloud
- Addition of cloud data storage and Pod's firmware update over the air (FOTA)
- Pod microcontroller change
- Pod outer design change

Otherwise, the device materials, principle of operation, and intended use remain the same as the predicate. Additionally, the changes do not raise different questions of safety or effectiveness.

Vibrant System Comparison Table

	Predicate Vibrant System (DEN210052)	**Subject Vibrant System (K223031)**
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.	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.
Population	Adults	Adults
Components	Pod, capsule	Pod, capsule, cloud software
Pod		
Pod Specifications, mm	86x83x38	65(dia.)x65(ht.)
ON Indicator	Green LED	Blue LED
Pod-Capsule Communication	RF	RF
Pod-Cloud Communication	None	GSM
Capsule Calibration	Upon placement in designated groove	During capsule production
Capsule Specifications	Length: 24.5 mm Diameter: 11.20 mm Weight: 4.0 g	Length: 24.5 mm Diameter: 11.20 mm Weight: 4.0 g
Capsule External Material	PC Makrolon 2458	PC Makrolon 2458

Performance Data

The following performance data was provided in support of the device modifications:

- Transportation and distribution validation per ASTM D4332-14, Standard Practice For Conditioning Containers, Packages, or Packaging Components for Testing and ASTM D4169-22, Package Integrity Testing
- Software documentation and validation per IEC 62304:2006/A1:2016 - Medical Device Software - Software Life Cycle Processes
- Cybersecurity validation
- IEC 60601-1, General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2, General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-11, General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- FCC Part 15, Sub-part C, section 15.209, Radiated emission limits; general requirements
- Bench performance testing to verify Pod meets visual and functional specifications

Conclusions

The provided performance testing demonstrates that the Vibrant System is as safe, as effective, and performs as the predicate device. Therefore, the Vibrant System is substantially equivalent.