December 8, 2023

Vibrant Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
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Re: K232830
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: September 13, 2023
Received: September 13, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephanie Cole -S

for Glenn B. Bell, PhD
Division Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
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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 below.

510(k) Number *(if known)*
K232830

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's Vibrant System

Submitter

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Date: September 13, 2023

Trade Name : Vibrant System

Regulation Name: Orally Ingested Transient Device For Constipation

Regulation Number: 21 CFR 876.5940

Regulatory Class: II

Product Code: QTN

Predicate Device
Vibrant Ltd.'s Vibrant System (K223031)

A. 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.

B. 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.

C. Summary of Technological Characteristics

The following changes are being made in this 510(k) with respect to the predicate:

- An optional change in the frequency of administration. While the labeling in the predicate (K223031) recommends a dosing of 5 times a week, the Vibrant System includes an alternative dosing option of 2 times/week (in addition to the 5 times a week dosing option).
- The modified Vibrant capsule includes an adaptive delay mechanism. This feature involves the automatic delay in stimulation start time of the capsule.
- There is also a change to the raw materials used for the capsule shell component of the device.

Performance testing and the clinical study confirm that these changes do not adversely impact performance with respect to safety or effectiveness, and the device continues to meet the same special controls as the predicate.

Table 1, comparing the key features of the subject and predicate devices is provided below.

Table 1: Key Features of the Subject and Predicate Devices

	Predicate Vibrant System (K223031)	**Subject Vibrant System**
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.	Same
Population	Adults	Same
Components	Pod, capsule, cloud software	Same
Pod-capsule Communication	RF	Same
Pod- Cloud Communication	GSM	Same
Capsule Calibration	During capsule production	Same
Capsule Specifications	Length: 24.5 mm Diameter: 11.20 mm Weight: 4.0 g	Same
Capsule Components	Coin vibration motor, electronic card, batteries (2 x 1.5v 60mAh), and connector, all encapsulated in a 2-piece shell	Same
Capsule External Material	PC Makrolon 2458	Makrolon 2458 010110

	Predicate Vibrant System (K223031)	Subject Vibrant System
Vibration Cycle	190 vibration cycles/ hour; each cycle: 3 sec. vibration and 16 sec. of repose (rest). The duration of each vibration cycle set alternates between 100 minutes (sets 1 and 3), 120 minutes (set 2), and 180 minutes (set 4).	Same
Adaptive delay mechanism	None. Device has a set delay mechanism of 14 hours since activation.	If device is taken at the wrong time, the device automatically adjusts the delay, ensuring the stimulation happens at the intended time.
Dosage	5 times weekly	Two dosage options: - 5 times weekly **or** - twice weekly

D. Summary of Nonclinical/Bench Studies

The Vibrant System conforms to the following relevant standards:

- ASTM D4332-14 - Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ANSI AAMI ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI IEC 62304:2006/A1:2016 - Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- ANSI AAMI IEC 60601-1-2:2014 - Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- IEC 60601-1-11 Edition 2.0 2015-01 - Medical electrical equipment - Part 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, Subpart C, Section 15.209: Unlicensed Wireless Devices Compliance Testing

In addition, the performance of the modified Capsule was evaluated with nonclinical bench testing as listed below.

- Mechanical Integrity when placed under loads
- Seal integrity
- pH Resistance
- Dimensional Verification of the capsules
- Visual Inspection for absence of surface defects and extraneous matter

E. Summary of Clinical Information

A clinical study was conducted, the objective of which was to assess the efficacy and safety of the Vibrant Capsule, administered 2 times a week. This was a prospective, randomized, multi-center, double-blinded, placebo-controlled study. The study enrolled 100 subjects. Study duration per patient included 8 weeks of treatment. Two arms were assessed (at a ratio of 1:1): (a) Vibrant Capsule, and (b) Placebo Capsule.

The study population was comprised of subjects with chronic idiopathic constipation (CIC) who were refractory to existing OTC or Rx treatments or could not tolerate the side effects.

There were two primary efficacy endpoints:

- CSBM1 success rate, defined as an increase of at least one weekly Complete Spontaneous Bowel Movement (CSBM) during at least 6 of the 8 weeks of treatment, and
- CSBM2 success rate, defined as an increase of at least two weekly CSBM during at least 6 of the 8 weeks of treatment.

Secondary efficacy endpoints included:

- Change from baseline in average straining.
- Increase of at least one weekly CSBM during at least 5 of the 8 weeks of treatment.
- Change from baseline in average stool consistency.
- Increase of at least two weekly CSBM during at least 5 of the 8 weeks of treatment.
- Change from baseline in average bloating.

Selected additional efficacy endpoints included increase of at least one weekly Spontaneous Bowel Movement during at least 6 out of 8 weeks of treatment and change in quality of life.

Safety endpoints include all adverse events related and unrelated to the study treatment.

Analysis sets: The Intend-to-Treat (ITT) analysis set consisted of all 100 subjects who were enrolled in the study and randomized. The Modified Intend-to-Treat (mITT) analysis set consisted of all 96 randomized subjects who met the inclusion criteria of the protocol.

Demographics: 100% (100/100) of the subjects were enrolled in US sites. 75% (75/100) of the participants were female, consistent with the expected gender distribution in the indicated population. The study participants were between 22.6 and 68.5 years old, with a mean age of 43.3 years (SD=12.27). The ethnic distribution was: Caucasian - 22%; Hispanic or Latino - 49%; Black or African American - 15%; Native American or American Indian - 2%; Asian/ Pacific Islander - 11%; Other - 1.0%.

No difference in gender or ethnicity between the treatment groups was considered to be statistically significant.

Primary Efficacy Results: **Table 2** presents the CSBM1 and CSBM2 success rates by study arm and analysis set. In the mITT analysis set, the CSBM1 success rate was higher in the active arm than in the placebo arm by 23.7%. The CSBM2 success rate was higher in the active arm than in the placebo arm, but the difference was not statistically significant. These results are repeated in the ITT analysis set as well.

Table 2: CSBM1 and CSBM2 Success Rates

		Active		Placebo		
		% (n/N)	**95% CI (Wilson Score)**	**% (n/N)**	**95% CI (Wilson Score)**	**p-value (CMH)**
mITT	**Imp. by at least 1 CSBM - 6 out of 8 weeks**	55.81% (24/43)	[41.11%;69.57%]	32.08% (17/53)	[21.09%;45.48%]	0.0161
	Imp. by at least 2 CSBM - 6 out of 8 weeks	30.23% (13/43)	[18.60%;45.11%]	22.64% (12/53)	[13.45%;35.53%]	0.5099
ITT	**Imp. by at least 1 CSBM - 6 out of 8 weeks**	54.55% (24/44)	[40.07%;68.29%]	30.36% (17/56)	[19.90%;43.34%]	0.0165
	Imp. by at least 2 CSBM - 6 out of 8 weeks	29.55% (13/44)	[18.16%;44.22%]	21.43% (12/56)	[12.71%;33.82%]	0.5091

Secondary and Additional Endpoints: While secondary endpoints, including quality of life, straining during bowel movements and stool consistency, were numerically higher in the Vibrant System group, the difference between the groups on these secondary assessments was not statistically significant.

Safety Analysis: A total of 42 Adverse Events (AE) were reported during the study, incidence of 16.00% and 19.64% in the active and placebo arm respectively. Eight AE's were considered possibly or related to the study treatment or procedure. Adverse events considered to be related to the use of the device were mostly limited to vibration/tickling sensations in the GI tract (1 case of mild headache was considered "possibly related"). The incidence of AE is decreased when compared to the clinical study presented in DEN210052 in which the device was taken 5 times/week. The decreased incidence in AE in the biweekly dosing study is expected as the dosing is reduced.

Overall, the study was deemed successful as the CSBM1 success rate was statistically significantly higher in the active arm than in the placebo arm.

Conclusion

Substantial equivalence of the subject Vibrant System compared to the predicate Vibrant System (K223031) was demonstrated by nonclinical and clinical performance testing provided in this 510(k) premarket notification. The same nonclinical testing was used to support the subject Vibrant System as was used for the predicate device. Similarly, although the modified system includes a labeling change that allows an optional change in dosing frequency, i.e. twice weekly administration, clinical testing demonstrates the device is as safe and effective when administered with this frequency as compared to the predicate. In addition, the subject Vibrant System continues to comply with the special controls set forth by FDA for this device type.

In conclusion, the modified Vibrant System is substantially equivalent to the currently marketed predicate device, Vibrant System (K223031), in terms of indications for use, technological characteristics, and safety and effectiveness.