July 8, 2019

ConTIPI Medical Ltd.
℅ Jonathan Kahan
Partner
Hogan Lovells US LPP
555 Thirteenth Street NW
Washington, DC 20004

Re: K190277
Trade/Device Name: ProVate Vaginal Support
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: HHW
Dated: June 7, 2019
Received: June 7, 2019

Dear Jonathan Kahan:

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,

Sharon Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190277

Device Name
ProVate Vaginal Support

Indications for Use *(Describe)*
The ProVate Vaginal Support is indicated for the temporary, nonsurgical management of Pelvic Organ Prolapse in females.

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

ConTIPI Medical Ltd.'s ProVate Vaginal Support

Submitter

ConTIPI Medical Ltd
2 Alon Ha'Tavor st. Caesarea Industrial Park,
POB 3135
Caesarea, Israel
Israel, 3088900

Phone: +972-4-6276066
Facsimile: +972-4-6276068
Contact Person: Tsvia Erlich, VP Regulatory & Clinical Affairs

Date Prepared: July 8, 2019

Name of Device:

ProVate Vaginal Support

Common or Usual Name:

Vaginal Pessary

Classification Name:

Vaginal pessary (21 CFR 884.3575)

Regulatory Class:

Class II

Product Code:

HHW (pessary, vaginal)

Predicate Devices

EIS Corporation, Pessary (K132313)

The predicate device has not been subject to a design related recall.

Device Description

The ProVate Vaginal Support is a vaginal ring pessary intended for the conservative nonsurgical, temporary management of Pelvic Organ Prolapse (POP) in females. The ProVate is a disposable, single use device intended to use for up to seven (7) days. The ProVate device is intended for prescription home use following a size fitting process performed by a health care professional.

The device is supplied in its compact mode, within a disposable Applicator intended for the insertion of the device. The device is expanded into its circular ring shape using the Applicator Plunger when inserting the device into the vagina. At the end of its use (up to 7 days), the patient pulls the Removal String which collapses the device into its compact configuration, facilitating easy removal. The device is then thrown away, and a new device can be inserted by the patient as needed.

The ProVate includes additional components to facilitate insertion and removal of the device. The ProVate device is constructed to allow insertion into the vagina by the patient while the device is in a compact mode contained within a single use applicator. The ProVate device is expanded to its circular shape using the applicator when inserted into the vagina. Once inserted, the circular shape of the ProVate is comparable to that of the predicate device and the ring provides support to the prolapsed organs. To remove the device, the ProVate includes a removal string. Pulling on the string collapses the device to its compact state allowing for easier and more comfortable removal.

Intended Use / Indications for Use

The ProVate Vaginal Support is indicated for the temporary, nonsurgical management of Pelvic Organ Prolapse in females.

Comparison of Technological Characteristics with the Predicate Device

The ProVate device is a ring vaginal pessary that is used to provide support to prolapsed organs, in a similar manner to the predicate. Both the ProVate pessary and the predicate pessary are ring shaped and are available in multiple sizes.

The main differences between the subject and predicate devices are:

- The predicate device is made of flexible materials (silicone) which allow the form to be moderately manipulated, while the subject device uses different polymer materials. However, the predicate does not incorporate the dual configuration design (collapsed and expanded state) of the subject device.
- The subject device is intended to be inserted and removed by the user in the home, while the predicate device is to be inserted initially by a physician with optional patient removal in the home following the initial use.
- The subject device is single use for up to 7 days (no cleaning) while the predicate is reusable with cleaning instructions.

These differences do not raise different questions of safety or effectiveness, and accepted test methods (e.g., biocompatibility, mechanical testing, vaginal microflora testing, and clinical testing) exist to assess the effects of these differences on device performance.

Performance Data

The following testing was conducted to evaluate the properties and performance of the device to confirm that the device meets its specifications:

- **Bench testing** was performed to confirm that the device met key performance specifications related to the functionality and safety of the device, such as, insertion and removal, device's and removal string's integrity, maximal forces, etc. The testing included the following:
  - Insertion Force
  - Removal Force
  - Directional compression
  - Repeatable directional compression
  - Extreme compression
  - Load on central Axis
  - String Detachment Force
  - Removal String Integrity
- **Shelf life study** to support two (2) years shelf life of the product
- **Biocompatibility testing** and chemical characterization of the device materials according to ISO 10993-1 and applicable FDA guidance documents. The following biocompatibility testing were conducted:

ISO Standard	Test	Results
10993-5	Cytotoxicity Study Using the ISO Elution Method	Non-cytotoxic
10993-10	ISO Guinea Pig Maximization Sensitization Test	Non-sensitizer
10993-10	ISO Vaginal Irritation Study in Rabbits	Non-irritant
10993-6	ISO Muscle Implantation Study in Rabbits – 4 Weeks and 10 Week	Macroscopic: Difference not significant; Microscopic: Non-irritant
10993-3	Genotoxicity: Bacterial Reverse Mutation Study	Non-mutagenic
10993-3	Genotoxicity: Mouse Lymphoma Assay	Non-mutagenic
10993-18	Toxicological Risk assessment	Acceptable risk of daily dose-exposure to compounds from device use

- **Evaluation of TSST-1 Risk** laboratory testing to evaluate the impact of the device on *Staphylococcus aureus* growth and TSST-1 production
- **Human factors label comprehension** validation study, by potential representative US users intended to evaluate the safety and suitability of

device labeling.

Clinical Testing

Two clinical studies were conducted on the ProVate device:

Prospective Safety Clinical Study. This prospective, statistically powered, multicenter, randomized, cross over study was intended to evaluate the impact of the ProVate device on vaginal microflora as compared to a control (US marketed vaginal pessary). Subjects used both the ProVate device and the control device in a cross over fashion following a wash out period. Vaginal examination and microbial evaluations were performed at the beginning and at the end of each usage phase (ProVate device and control). Safety was also assessed by an evaluation of adverse events. All study endpoints were met successfully. The primary endpoint in this study was met successfully showing non-inferiority of the ProVate Device with respect to changes in vaginal microflora when compared to an existing market available ring pessary. There was no device related serious adverse events. The majority of the adverse events were considered minor, transient and resolved with no sequalae.

Prospective Clinical Study to Evaluate Safety and Effectiveness. A statistically powered, one arm, multi clinic prospective study was performed to evaluate the safety and performance of the ProVate device. Following a fitting process performed by a physician, users used devices within their home environment. The study device was used in a home use environment and followed the clinical routine for the management of pessaries. Vaginal examinations were conducted during each visit to the study clinic.

The study demonstrated that the device resulted in an improvement from baseline of at least one stage in prolapse and an improvement in prolapse symptoms while in use. Subjects started with stage 2 or 3 level prolapse at baseline and had stage 0 or 1 prolapse with the device in place.

In addition, the device did not result in adverse events at a higher rate than that of predicate pessary devices. All device-related adverse events were mild and transient.

Conclusions

The performance data demonstrate that the ProVate is as safe and effective as the EIS Corporation Pessary predicate device.