February 27, 2023

Materna Medical
% Cindy Domecus, R.A.C.
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, CA 94010

Re: K220035
Trade/Device Name: Milli Vaginal Dilator
Regulation Number: 21 CFR§ 884.3900
Regulation Name: Vaginal Stent
Regulatory Class: II
Product Code: HDX
Dated: January 27, 2023
Received: January 30, 2023

Dear Cindy Domecus:

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220035

Device Name
Milli Vaginal Dilator

Indications for Use *(Describe)*
The Milli Vaginal Dilator is a tool intended for controlled dilation of the vagina. It can be used for dilation for an examination (by your doctor), in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus (condition that involves tightening of the vaginal muscles) and related painful sex.

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: K220035

I. SUBMITTER

Submitter:
Materna Medical, Inc.
2495 Hospital Drive, Suite 300
Mountain View, CA 94040
Phone: 866-433-6933

Contact: Kelly Ashfield

Submission Correspondent:
Cindy Domecus, R.A.C. (US & EU)
Principal
Domecus Consulting Services LLC
Cindy@DomecusConsulting.com

Date Prepared:

February 24, 2023

II. DEVICE INFORMATION

Name of Device:
Milli Vaginal Dilator

Common or Usual Name:
Vaginal Dilator

Classification Name:
Vaginal Stent (21 CFR 884.3900)

Regulatory Class:
II

Product Code:
HDX

III. PREDICATE DEVICE

The predicate device is the Milli Vaginal Dilator cleared under K211959. The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Milli Vaginal Dilator is a patient-controlled vaginal dilator that provides therapy for vaginal tightness through stretching of the vaginal tissue under electromechanical expansion, one millimeter at a time. The Milli Vaginal Dilator expands electronically in increments of 1mm from a baseline of 15mm to 40mm in diameter.

Dilation and contraction of the Milli Vaginal Dilator is at the control of the user with a simple button push of either the + or – buttons. The Milli Vaginal Dilator is a single vaginal dilator tool that encompasses the diameter range of many commercially available dilator sets, allowing the user to increase the diameter in smaller increments while the device remains inserted, eliminating the need for removal and insertion of larger sizes. The dilation setting is provided on the user interface to allow the user to easily track dilation progress. The Milli Vaginal Dilator also incorporates a vibration feature that may be used as desired to promote relaxation. The Milli Vaginal Dilator is battery powered and provided with a storing/charging case and a USB/adaptor to facilitate charging. The subject device is intended to be sold over the counter (OTC), to be purchased online without the support of a healthcare provider.

V. INDICATIONS FOR USE

The intended use of the subject device is identical to the predicate device. They are both intended for controlled dilation of the vaginal tissue for an examination, in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus and related dyspareunia. The Indications for Use of the subject and predicate device are shown below. The only modification to the language cleared in the Indications for Use for the Milli Vaginal Dilator (Rx) is to include some lay terms in the OTC indication.

Milli Vaginal Dilator (OTC) **Subject Device** **K220035**	**Milli Vaginal Dilator (Rx)** **Predicate Device** **K211959**
The Milli Vaginal Dilator is a tool intended for controlled dilation of the vagina. It can be used for dilation for an examination (by your doctor), in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus (condition that involves tightening of the vaginal muscles) and related painful sex.	The Milli Vaginal Dilator is a tool intended for controlled dilation of the vagina. It can be used for dilation for an examination, in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus and related dyspareunia.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the predicate device are unchanged. Therefore, the technological characteristics of the subject device are substantially equivalent to the predicate Milli Vaginal Dilator (Rx) cleared under K211959.

VII. PERFORMANCE DATA

The proposed and predicate device are technologically identical. As such, all necessary nonclinical performance testing conducted to support the clearance of the predicate Milli Vaginal Dilator (Rx) (K211959) are applicable to the subject 510(k).

Nonclinical Testing Summary:

The nonclinical performance testing that supports the clearance of the subject device included the following:

- Shelf-Life Storage and Packaging (Transit) Testing
- Biocompatibility Testing
- Software Verification Testing
- Electromagnetic Compatibility and Electrical Safety Testing
- Size and Dilation Design Verification
- Charging/Cleaning Verification
- Reliability Testing
- Engineering Evaluation

The collective results of the nonclinical performance testing demonstrate that the materials chosen, the manufacturing processes, and design of the Milli Vaginal Dilator meet the established specifications necessary for consistent performance for its intended use.

Clinical Testing Summary:

A self-selection study was conducted to assess whether potential users of the Milli Vaginal Dilator could accurately determine if they were indicated for use of the Milli Vaginal Dilator based on the device labeling (website).

The study was a prospective, single-arm, multi-center, single-blinded study enrolling subjects who were prospective users of the Milli Vaginal Dilator. The study enrolled 25 subjects, all of whom completed the study per protocol.

The study assessed, via independent review of a mock Milli ordering website, and follow up questionnaires, whether prospective users of the Milli Vaginal Dilator could accurately determine if they were indicated for the Milli Vaginal Dilator without the support of a Health Care Professional (HCP). This was determined by a comparison of the subject's unaided self-assessment with the assessment by the healthcare professional, after an in-person evaluation of the subject and blinded to the subject's prior self-assessment.

The results demonstrated that 96% (24 of 25) of the potential users of the Milli Vaginal Dilator could correctly determine whether they are appropriate candidates for use of the device, based on review of the Milli ordering webpage prior to purchase, and therefore provides sufficient information to support that OTC use of the Milli Vaginal Dilator is as effective as prescription use of the device.

VIII. CONCLUSIONS

The subject device and the predicate device have the same intended use and technological characteristics. The differences in the Indications for Use statement do not raise different questions of safety and effectiveness. A self-selection study was conducted to support substantial equivalence of device effectiveness by evaluating self-diagnosis in the OTC population as compared to diagnosis by an HCP for the OTC indication of the subject device; in addition, a risk analysis concluded that there were no new risks for the OTC indication. Therefore, the Milli Vaginal Dilator for OTC use is substantially equivalent to the predicate Milli Vaginal Dilator for Rx use cleared under K211959.