December 1, 2021

Materna Medical
% Valerie Defiesta-Ng
Vice President, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K211959
Trade/Device Name: Milli Vaginal Dilator
Regulation Number: 21 CFR 884.3900
Regulation Name: Vaginal Stent
Regulatory Class: II
Product Code: HDX
Dated: October 29, 2021
Received: November 1, 2021

Dear Valerie Defiesta-Ng:

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 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)*
K211959

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, in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus and related dyspareunia.

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

510(k) Notification K211959

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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

Contact Person:

Valerie Defiesta-Ng
Vice President, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110

Date Prepared:

November 30, 2021

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Milli Vaginal Dilator

Generic/Common Name:

Vaginal Dilator

Regulation Number:

21 CFR§884.3900

Regulation Name:

Vaginal Stent

Regulatory Class:

II

Product Code:

HDX

PREDICATE DEVICE [807.92(a)(3)]

Primary Predicate Device: Panpac Vaginal Dilators (K130273)

Reference Device: Amielle Vaginal Dilator (K983045)

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

510(k) SUMMARY (CONT.)

DEVICE DESCRIPTION [807.92(a)(4)]

The Milli Vaginal Dilator is a patient-controlled vaginal dilator that provides therapy through distention of the vaginal tissue under electromechanical expansion. The device is intended for use for adult women (≥18 years) who need controlled vaginal dilation for an examination, in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus and related dyspareunia. 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 are completed by 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. 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. The Milli Vaginal Dilator is battery powered and provided with a storing/charging case and a USB/adaptor to facilitate charging.

The Milli Vaginal Dilator is intended for use in a home or healthcare environment. The device is intended for prescription (Rx) use, and the treatment duration, frequency, and length are specified in the Instructions for Use and/or at the discretion of the physician.

INDICATIONS FOR USE [807.92(a)(5)]

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [807.92(a)(6)]

The proposed device and the predicate device have the same Intended Use and similar Indications for Use. The Milli Vaginal Dilator, the primary predicate device, the Panpac Vaginal Dilator, and the reference device, the Amielle Vaginal Dilator, are intended for gradual dilation of the vaginal tissue for vaginismus and related dyspareunia.

The proposed and predicate device share key technological similarities, as they are each intended for gradual dilation of the vaginal tissue in the home or healthcare environment. Please see Table 1 below for a detailed technological comparison. The differences in technology of the Milli Vaginal Dilator as compared to the predicate do not raise different questions of safety or effectiveness, and can be evaluated through performance testing, as summarized below.

PERFORMANCE DATA [807.92(b)]

All necessary bench testing was conducted on the Milli Vaginal Dilator to support a determination of substantial equivalence to the predicate device. All Nonclinical Bench Performance Testing performed for the Milli Vaginal Dilator passed the prespecified acceptance criteria/design inputs.

510(k) SUMMARY (CONT.)

NONCLINICAL BENCH PERFORMANCE TESTING SUMMARY [807.92(B)(1)]

The Nonclinical Bench Performance Testing included:

- 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 Bench 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. The results of performance testing demonstrate that differences in technological characteristics between the Milli Vaginal Dilator and the Panpac Vaginal Dilator do not raise any different questions of safety and effectiveness.

CLINICAL TESTING SUMMARY [807.92(B)(2)]

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

CONCLUSIONS [807.92(b)(3)]

The proposed device and the predicate device have the same Intended Use and similar Indications for Use. Furthermore, the proposed and predicate device share key technological similarities. The technological differences presented with the proposed device do not raise different questions of safety or effectiveness as compared to the predicate, and the performance testing on the proposed device demonstrate it is as safe and as effective as the predicate device.

SUMMARY

The Milli Vaginal Dilator is substantially equivalent to the predicate device.

510(k) SUMMARY (CONT.)

Table 1: Substantial Equivalence Table

Device Name	Milli Vaginal Dilator (Subject Device)	Panpac Vaginal Dilator (Primary Predicate)	Amielle Vaginal Dilator (Reference Device)	Rationale for Substantial Equivalence
510(k) Number	K211959	K130273	K983045	-
Company	Materna Medical, Inc.	Panpac Medical Corporation	Owen Mumford, Ltd.	-
Classification	21 CFR§884.3900: Vaginal stent	21 CFR§884.3900: Vaginal stent	21 CFR§884.3900: Vaginal stent	Same
Product Code	HDX: Dilator, Vaginal	HDX: Dilator, Vaginal	KXP: Stent, Vaginal	Same as the Panpac Vaginal Dilator, primary predicate. Similar to the Amielle Vaginal Dilator, reference device.
Indications for Use	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.	Panpac Vaginal Dilators are **indicated for women who need vaginal dilation for an examination, a surgical procedure, or for the relief of vaginismus**. Panpac Vaginal Dilators has four different size (small, medium, large and extra large) in three family types; Family A, Family B and Family C with variant sizes.	The device is **intended to treat women suffering from vaginismus and dyspareunia**. VAGINISMUS is the involuntary spasm of the muscles in the vaginal wall which then inhibits sexual intercourse by making it painful or impossible. DYSPAREUNIA is the pain experienced during sexual intercourse caused by physical and/or emotional problems. The device comes in varying sizes, the most appropriate is then selected by the physician for use by the patient and the patient's partner as an assistant if appropriate. **It is used as a tool to DILATE the vagina in controlled stages.** The device can be autoclaved or sterilized by normal methods.	Similar; same intended use.
Single Use	Reusable 5-30 minutes/day	Reusable 5-30 minutes/day	Daily use recommended; dilator is intended to be left in position for up to 5 minutes	Same as the primary predicate. Similar to the reference device.
Prescription/ Over-the-Counter	Prescription Use	Prescription Use	Prescription Use	Same

510(k) SUMMARY (CONT.)

Device Name	Milli Vaginal Dilator (Subject Device)	Panpac Vaginal Dilator (Primary Predicate)	Amielle Vaginal Dilator (Reference Device)	Rationale for Substantial Equivalence
Primary Mode of Action	Passive stretching through electromechanical increase in size	Passive stretching through use of increasingly sized dilators	Passive stretching through use of increasingly sized dilators	Similar; electromechanical size change vs. use of differently sized dilators. The difference in the primary mode of action does not raise different questions of safety or effectiveness; performance is demonstrated by Nonclinical Bench Performance Testing.
Design	Single dilator (shown fully closed and expanded to display the range of dilation size) 	Fixed shape design with different sizes; multiple reusable dilators required 	Fixed shape design with different sizes; multiple reusable dilators required 	Similar; single dilator with gradual size change vs. use of differently sized dilators.
Dilation Size (Outer Diameter)	15-40mm	13-38mm	15-35mm	Similar, within the dilation range of the primary predicate and reference device.
Dilation Jumps	1mm	1-6mm	5mm	Similar; more gradual dilation jumps with the Milli Vaginal Dilator.
Energy Source	Rechargeable lithium-ion battery (3.7V)	None	None	Different. This technological difference does not raise different questions of safety or effectiveness; performance is demonstrated by IEC 60601-1 testing.
Software	The Milli Vaginal Dilator contains basic firmware to dilate/contract and to turn vibration option on/off.	No software	No software	Different. This technological difference does not raise different questions of safety or effectiveness; performance is demonstrated by software verification testing.
Environment for use	Home or healthcare environment	Home or healthcare environment	Unspecified; likely same	Same

510(k) SUMMARY (CONT.)

Device Name	Milli Vaginal Dilator (Subject Device)	Panpac Vaginal Dilator (Primary Predicate)	Amielle Vaginal Dilator (Reference Device)	Rationale for Substantial Equivalence
Sterility	Nonsterile	Nonsterile	Nonsterile	Same
Nonclinical Bench Performance Testing/In Vitro Bench Testing	• Size and Dilation Testing • Charging/Cleaning Testing • Reliability Testing • Engineering Evaluation • Shelf Life Storage and Packaging (Transit) Testing	Testing unknown, not specified in 510(k) summary or marketing materials.	Testing unknown, not specified in 510(k) summary or marketing materials.	Testing for the primary predicate and reference device is unknown, as it is not specified in the 510(k) summaries or marketing materials.
Electrical Safety and EMC Testing	Testing conducted in accordance with 60601-1, 60601-1-6, 60601-1-11 and 60601-1-2.	Testing Not Applicable	Testing Not Applicable	Different. This difference does not raise different questions of safety or effectiveness.
Biocompatibility Testing	Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, and Biological Risk Assessment Conducted	Testing unknown, not specified in 510(k) summary or marketing materials.	Testing unknown, not specified in 510(k) summary or marketing materials.	Testing for the primary predicate and reference device is unknown, not specified in 510(k) summary or marketing materials. Risk management for the proposed device informed the biocompatibility testing.
Clinical Testing	No clinical testing conducted to support clearance.	No clinical testing conducted to support clearance.	No clinical testing conducted to support clearance.	Same