July 5, 2023

Lujena, Inc.
% Alan Donald
President
Matrix Medical Consulting, Inc.
8880 Rio San Diego Drive, Suite 800
San Diego, CA 92108

Re: K222492
Trade/Device Name: Hope&Her Vaginal Dilators
Regulation Number: 21 CFR§ 884.3900
Regulation Name: Vaginal Stent
Regulatory Class: II
Product Code: HDX

Dear Alan Donald:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 27, 2023. Specifically, FDA is updating this SE Letter to correct the contact information in the 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jason Roberts, Ph.D., OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (240) 402-6400, Jason.Roberts@fda.hhs.gov.

Sincerely,

Reginald K. Avery -S

for
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

June 27, 2023

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President
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Re: K222492
Trade/Device Name: Hope&Her Vaginal Dilators
Regulation Number: 21 CFR§ 884.3900
Regulation Name: Vaginal Stent
Regulatory Class: II
Product Code: HDX
Dated: May 24, 2023
Received: May 24, 2023

Dear Alan Donald:

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,

Reginald K. Avery -S

for
Monica D. Garcia, 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)*
K222492

Device Name
Hope&Her Vaginal Dilators

Indications for Use *(Describe)*
Hope&Her Vaginal Dilators are indicated for women who need vaginal dilation for an examination, in preparation for a surgical procedure, or for the relief of vaginismus.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary – K222492
Hope&Her Vaginal Dilators

I. General Information on Submitter

Applicant:	Lujena, Inc.
Address:	772 Jamacha Road. #800 El Cajon, CA 92019
Telephone:	1 619 449 1200
Contact Person:	Troy Gemmer
Contact Title:	President Lujena, Inc.
Email:	lujena@icloud.com
Date Prepared:	June 15, 2023

II. General Information on Device

Name of Device:	Hope&Her Vaginal Dilators
Dilators Common of Usual Name:	Vaginal Dilators
Regulation Number:	21 CFR 884.3900
Classification Name:	Vaginal Stent
Regulatory Class:	II
Product Code:	HDX (Dilator, Vaginal)
Classification Panel:	Obstetrics/Gynecology

III. Predicate Device

Predicate Device	510(k) Number
Amielle	K983045

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

IV. Description of Device

Hope&Her Vaginal Dilators is a series of reusable, non-sterile, single user vaginal dilators that are used by patients to provide passive distention of the vaginal tissues using various sized dilators. The subject device has various sized rigid dilators that range from 15 mm to 38 mm in diameter (15, 22, 26, 30, 34, and 38 mm) and a handle to hold the dilator. The subject device is prescription-only. The subject device is composed polyester and polyamide. The subject device is distributed in heat-seal plastic bags.

V. Indications for Use

Hope&Her Vaginal Dilators are indicated for women who need vaginal dilation for an examination, in preparation for a surgical procedure, or for the relief of vaginismus.

Differences in Indications for Use:

Subject device: “Hope&Her Vaginal Dilators are indicated for women who need vaginal dilation for an examination, in preparation for a surgical procedure, or for the relief of vaginismus.”

Predicate device: “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.”

The difference between the subject and predicate device indications for use is that the predicate device includes additional indications for dyspareunia and also includes technological description of the device. As the subject device indications are a subset of the predicate device indications, this difference does not raise intended use concerns.

VI. Comparison of Technological Characteristics with the Predicate Device

	SUBJECT DEVICE K222492	PREDICATE DEVICE K983045
Device Name	Hope&Her Vaginal Dilators	Amielle
Regulation Number	21 CFR§ 884.3900	21 CFR§ 884.3900
Regulation Name	Vaginal Stent	Vaginal Stent
Regulatory Class	II	II
Over the Counter	No	No
Feature	Vaginal dilator, controlled stages	Vaginal dilator, controlled stages
Target Population	Women suffering from vaginismus	Women suffering from vaginismus and dyspareunia
Anatomical Site	Vagina	Vagina
Single Patient Device	Yes	Yes
Reusable	Yes	Yes

Sterile	Non-sterile	Non-sterile
Device Design	Conical	Conical
Materials	Polyester and polyamide	Polybutylene terephthalate dilator
Diameter	Available from 15 - 38 mm; increases diameter in metrics of 4 - 7 mm	Available from 15 – 35 mm; increases diameter in metrics of 5 mm
Packaging	Packaged in heat-sealed bag with instructions for use.	Packaged in a cardboard box with instructions for use.
Operating Principle	Dilate the vagina in controlled stages	Dilate the vagina in controlled stages
Resistive component	Progressively larger dilators	Progressively larger dilators
Maintenance	Clean with mild soap and boiling water. Towel dry.	Clean with mild soap and hot water. Towel dry.
Color	White and turquoise	White
Biocompatibility Testing	Yes	Yes

As noted in the table above, the subject device and predicate device are similar in all aspects, except for differences in target population, materials, dimensions, packaging, maintenance, and color. These differences do not raise different questions of safety or effectiveness and can be evaluated through performance testing.

VII. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing on the vaginal dilators was performed in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009/(R)2014)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2010)
- Vaginal Irritation (ISO 10993-23: 2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrate that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Reprocessing

The device labeling included reprocessing information per FDA's 2015 guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

Physical Properties

The following device characteristics were evaluated for the subject device:

- Appearance
- Diameter
- Tensile strength

VIII. Conclusion

Based on the results of the performance testing described above, the Hope&Her Vaginal Dilators are as safe and effective as the predicate device and supports a determination of substantial equivalence.