June 23, 2023

Rosesta Medical BV
℅ Jill Matzat
CEO
CRA Solutions, Inc.
6250 Coral Ridge Drive, Suite 100
Coral Springs, FL 33076

Re: K222969
Trade/Device Name: FERTI.LILY Conception Cup
Regulation Number: 21 CFR§ 884.5250
Regulation Name: Cervical Cap
Regulatory Class: II
Product Code: HDR
Dated: May 19, 2023
Received: May 22, 2023

Dear Jill Matzat:

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,

Michael T. Bailey -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)*
K222969

Device Name
FERTI.LILY Conception Cup

Indications for Use *(Describe)*
The FERTI.LILY Conception Cup is indicated for over-the-counter home use. It is for couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. After intercourse, the FERTI.LILY Conception Cup is placed around the cervix. It retains semen near the cervical os (the passage between the vaginal cavity and the uterus) as an aid to conception. The FERTI.LILY Conception Cup should be used during the ovulatory phase of the menstrual cycle. The FERTI.LILY Conception Cup should not be left in place for longer than one hour.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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
K222969
FERTI.LILY Conception Cup

1. Submitter Information

Applicant:	Rosesta Medical BV
Address:	Mr. Treublaan 7, 1097DP Amsterdam, The Netherlands
Contact:	Robert Stal
Phone:	+31622377804
Email:	robert@rosesta.com

2. Submission Correspondent

Company:	CRA Solutions, Inc
Contact:	Jill Matzat
Phone:	(954) 778-0146
Email:	jmatzat@cra-training.com

3. Date prepared: June 22, 2023

4. Device Information

Device Name:	FERTI.LILY Conception Cup
Common Name:	Cervical Cap
Regulation Number:	21 CFR 884.5250
Regulation Name:	Cervical Cap
Product Code:	HDR (Cap, Cervical)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Oves Cervical Cap
510(k) Number:	K993953
Sponsor:	Veos Ltd.

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

6. Device Description

The FERTI.LILY Conception Cup is a non-sterile, silicone, over-the-counter (OTC) device for use by couples as an aid to conception that have been unable to get pregnant naturally due to low sperm count, low sperm motility, or an unfavorable vaginal environment. After intercourse, the device is placed in the vagina, the cup-like receptable is deployed using an integrated deployment cord, and the device is positioned over the cervix to physically situate semen near the cervical os. The FERTI.LILY Conception Cup can be left in the vagina for a maximum duration of one hour.

The FERTI.LILY Conception Cup includes a stem to assist with removal from the vagina.

7. Indications for Use Statement

The FERTI.LILY Conception Cup is indicated for over-the-counter home use. It is for couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. After intercourse, the FERTI.LILY Conception Cup is placed around the cervix. It retains semen near the cervical os (the passage between the vaginal cavity and the uterus) as an aid to conception. The FERTI.LILY Conception Cup should be used during the ovulatory phase of the menstrual cycle. The FERTI.LILY Conception Cup should not be left in place for longer than one hour.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	K222969	K993953	Comparison
Device Name	FERTI.LILY	Oves Cervical Cap	--
Device Classification	II	II	Same
Product Code	HDR	HDR	Same
Indications for Use	The FERTI.LILY Conception Cup is indicated for over-the-counter home use. It is for couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. After intercourse, the FERTI.LILY Conception Cup is placed around the cervix. It retains semen near the cervical os (the passage between the vaginal cavity and the uterus) as an aid to conception. The FERTI.LILY	The oves cervical cap is indicated for use in artificial insemination procedures in situations in which low sperm count, sperm immotility, or hostile vaginal environment have been diagnosed. The oves cervical cap removes semen from the vaginal environment and concentrates the sperm at the opening of the cervical os, thus facilitating sperm contact with cervical mucosa.	The subject and predicate device indications are not identical. Differences include the subject device is for OTC home use while the predicate is for prescription use in a clinical setting. Also, the subject device is used after intercourse, while the predicate is loaded before vaginal placement. The differences between the indications for use for the two devices do not represent a new intended use as both devices are intended to maintain a pool of semen/sperm near the cervical os as an aid to conception.

	Conception Cup should be used during the ovulatory phase of the menstrual cycle. The FERTI.LILY Conception Cup should not be left in place for longer than one hour.		
Sterile	No (non-sterile)	Not known	**Different:** Information regarding predicate device sterility is not known. However, differences in sterility for these vaginal-use devices do not raise different questions of safety and effectiveness (S&E)
Device components	Cervical Cup, storage bag	Cervical Cap	Similar
Use environment	OTC, home environment	RX, clinical environment	**Different:** The difference in use environment of the subject and predicate devices do not raise different questions of S&E.
Patient Population	Couples with low sperm motility, low sperm count, or unfavorable vaginal environment	Couples with low sperm motility, low sperm count, or unfavorable vaginal environment	Same
Patient Contact Material	Silicone	Silicone	Same
Cap loading	Placed in vagina after intercourse	Semen added to cap before placement	**Different:** The subject device is placed after intercourse, while the predicate is loaded with sperm before delivery. These differences do not raise different questions of S&E (e.g., device design maintains sperm near the cervical os to aid in conception).

Human Sperm Survival Assay (HSSA) Conducted	Yes, ≥ 80% motility after 2-hour exposure to the Conception Cup	Not known	**Different –** Testing assessing the compatibility of the predicate device with sperm is not known. This difference between the subject and predicate device does not raise different questions of S&E.
Wear time	≤ 1 hours	Not known	**Different:** Information regarding predicate device wear time is not known. The difference in wear-time between the subject and predicate device does not raise different questions of S&E.
Shelf-life	Shelf Life: 36 months	Not known	**Different -** The predicate device shelf-life is not known. Differences in shelf-life duration do not raise different questions of S&E.
Reprocessing and Reuse	Use Life: 3 months Device is reprocessed between uses.	Single-use only	**Different –** The predicate device is for single use only, while the subject device can be reprocessed and re-used. These differences do not raise different questions of S&E
Dimensions	Cap Dimensions: OD: 1.27 ± 0.05 in Cap Depth: 0.85 ± 0.035 in Total length (with retrieval): 4.33 ± 0.05 in	Not known	**Different –** The predicate device dimensions are not known. Differences in dimensions do not raise different questions of S&E.
Volume	13.8 ± 0.3 mL	Not known	**Different** – The volume of the predicate device is not known. Differences in volume do not raise different questions of S&E.

The subject and predicate devices do not have identical indications for use or technological characteristics. As noted above, the differences in indications for use do not represent a new intended use. In addition, the

technological differences identified in size, wear-time, delivery method (i.e., after intercourse vs. loading before delivery), re-use vs. single use, sperm testing methods, etc. do not raise different questions of safety and effectiveness as compared to the predicate device.

9. Summary of Non-Clinical Performance Testing

Biocompatibility:
Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization testing were 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)
- Sensitization (ISO 10993-10:2010/R 2014)
- Vaginal Irritation (ISO 10993-10:2010/R 2014)
- Acute Systemic Toxicity (ISO 10993-11:2017)

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

Shelf Life:
A real-time shelf-life study was performed to verify that the FERTI.LILY Conception Cup maintained its specifications over its entire 36-month shelf-life. Specifications assessed in support of device shelf-life include the following:

- Device Color
- Device appearance
- Device odor
- Dimensional specifications
- Volume
- Tensile testing (force at break and elongation)
- Hardness (Shore A)
- Human Sperm Survival Assay (HSSA)

Reprocessing:
Reprocessing validation was conducted per the 2015 FDA guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff.* This validation was conducted with residual protein and residual total organic carbon (TOC) analysis on a robust sample of devices to ensure protein and carbon residuals did not remain on the FERTI.LILY Conception Cup after full reprocessing.

Use-Life:
The FERTI·LILY Conception Cup has a use-life of three months. Testing below was conducted on newly manufactured devices and devices after maximum simulated deployment and reprocessing steps in accordance with the Instructions for Use. Devices were within specification range for each assessed parameter shown below:

- Device Color
- Device appearance

- Device odor
- Dimensional specifications
- Volume
- Tensile testing (force at break and elongation)
- Hardness (Shore A)
- Human Sperm Survival Assay (HSSA)

10. Summary of Clinical Performance Testing

Data from four clinical studies was used to support the following assessments: Self-Selection, Label Comprehension, and Actual Use Usability testing for the FERTI.LILY Conception Cup to support OTC at home use of the device.

First Study: A self-selection, label comprehension, and virtual simulated use study for the FERTI-LILY Conception Cup was conducted to demonstrate that the target intended use population achieved acceptable comprehension of the device labeling. Seventy-five naïve subjects were enrolled and 74 subjects completed the full study protocol. The prespecified target comprehension level of 80% for each knowledge endpoint related to self-selection, label comprehension and simulated-use was met, but there were some limitations in the designation of critical tasks related to device reprocessing and re-use.

Second Study: A second labeling comprehension study was conducted to support labeling revisions in a diverse study population. Forty-one (41) naïve subjects completed the full study protocol. The target comprehension level (80%) of each knowledge endpoint tested was met.

Third Study (FCC-001): This study was conducted to evaluate the usability and label comprehension of the FERTI.LILY Conception Cup. Fifteen (15) subjects were enrolled and each demonstrated clear understanding of the package directions. The at-home usability component demonstrated that 87% of subjects were able to successfully insert the device. Transient non-serious adverse events (discomfort, irritation, cramping) were reported but did not require any treatment. A user experience survey within the study showed that subjects reported high ease of use and satisfaction with the device.

Fourth Study (FCC-002): This study was conducted to evaluate the usability and safety of the FERTI.LILY Conception Cup. Fifteen (15) subjects were enrolled and all 15 subjects were able to successfully use the device in both in-clinic (simulated use) and at-home (actual real-world use) settings. All (100%) subjects correctly inserted the device, and no device-related adverse events or device deficiencies were observed.

Furthermore, the clinical usability studies assessed the following endpoints:

- Correctly follow all instructions prior to placement in the vagina (reprocessing, wash hands before touching device, etc.)
- Correctly insert the device into the vagina after sexual intercourse
- Correctly deploy and position the device over the cervical os (assessed by physician)
- Correctly avoid sexual activity while the device is in place and wear the device for the maximum amount of time (one hour)
- Assess leakage of semen from the vagina during the one-hour wear duration.
- Correctly remove the device from the vagina
- Health care provider (HCP) or physician assessment and documentation of the volume of semen remaining in the cup after the user removes it.
- HCP assessment for potential vaginal injury/trauma following user removal of the device,

capturing information on events occurring during use (discomfort, dislocation, device breakage/damage, etc.).
- Correctly reprocess the device after the actual use period

This study found that all 15 subjects were able to successfully use the device in both in-clinic and at-home settings, with all above outcomes met, demonstrating simulated use and real world use respectively.

In conclusion, the clinical studies demonstrated that the intended use population across different health literacy levels was able to comprehend the FERTI.LILY Conception Cup labeling and the intended use of the device. The study population also reported demographic information representative of the US population and successfully completed all elements of the studies.

11. Conclusion

The results of the non-clinical and clinical performance testing described above demonstrate that the FERTI.LILY Conception Cup is as safe and effective as the predicate device and supports a determination of substantial equivalence.