April 2, 2025

StepOne Fertility Ltd (t/a Béa Fertility)
Tom Littleford
Quality Assurance Manager
71-75 Shelton Street
Covent Garden
London, WC2H 9JQ
UNITED KINGDOM

Re: K242031
Trade/Device Name: Béa Applicator (BAP-GB-01)
Regulation Number: 21 CFR 884.5250
Regulation Name: Cervical Cap
Regulatory Class: II
Product Code: HDR
Dated: July 11, 2024
Received: March 3, 2025

Dear Tom Littleford:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242031

Device Name
Béa Applicator

Indications for Use *(Describe)*
The Béa Applicator is indicated for over-the-counter home use by couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. The Béa Applicator contains a Béa Cervical Cap which is used to contain, deliver, and retain semen near the cervical opening as an aid to conception. The Béa Applicator should be used during the ovulatory phase of the menstrual cycle. The Béa Cervical Cap should not be left in place for longer than 5 hours.

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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510(k) Summary
K242031
Béa Applicator

1. Submitter Information

Applicant:	StepOne Fertility Ltd (t/a Béa Fertility)
Address:	71-75 Shelton Street Covent Garden London WC2H 9JQ United Kingdom
Contact:	Dr. Tom Littleford
Phone:	+447543155529
Email:	tom@beafertility.com

2. Date prepared:

March 31, 2025

3. Device Information

Device Name:	Béa Applicator
Common Name:	Cervical Cap
Regulation Number:	21 CFR 884.5250
Regulation Name:	Cervical Cap
Product Code:	HDR (Cap, Cervical)
Regulatory Class:	Class II

4. Predicate Device Information

Device Name:	FERTI.LILY Conception Cup
510(k) Number:	K222969
Sponsor:	Rosesta Medical BV

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

5. Device Description

The Béa Applicator is an 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. The Applicator is provided to the users pre-assembled with the silicone cervical cap and a funnel to guide the semen into the cervical cap. Semen is poured from a sterile semen container into the cervical cap, which is located in the Applicator. The user inserts the Applicator into the vagina and deploys the cervical cap at or near the cervix by turning the handle. The Applicator is removed from the vagina and the cervical cap is left for up to five (5) hours to allow sperm to travel through the cervical canal. The user then removes the cervical cap from the vagina using its attached retrieval string and disposes of it. All components of the Béa Applicator are single-use only. The applicator and cervical cap components are non-sterile, while the semen collection container is provided sterile.

6. Indications for Use Statement

The Béa Applicator is indicated for over-the-counter home use by couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. The Béa Applicator contains a Béa Cervical Cap which is used to contain, deliver, and retain semen near the cervical opening as an aid to conception. The Béa Applicator should be used during the ovulatory phase of the menstrual cycle. The Béa Cervical Cap should not be left in place for longer than 5 hours.

7. 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.

	K242031	**K222969**	**Comparison**
Device Name	Béa Applicator	FERTI.LILY	--
Device Classification	II	II	Same
Product Code	HDR	HDR	Same
Indications for Use	The Béa Applicator is indicated for over-the-counter home use by couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. The Béa Applicator contains a Béa Cervical Cap which is used to contain, deliver, and retain semen near the cervical opening as an aid to conception. The Béa Applicator should be used during the ovulatory phase of the menstrual cycle. The Béa Cervical Cap should not be left in place for longer than 5 hours.	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	Same intended use to maintain semen near the cervical opening 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	Applicator/funnel, Cervical cap – Non-sterile Semen collection container – sterile	No (non-sterile)	**Different:** Differences in sterility for these vaginal-use devices do not raise different questions of safety and effectiveness (S&E).
Device components	Pre-assembled applicators, semen collection containers	Cervical cup, storage bag	**Different:** These differences in device components do not raise different questions of S&E.
Use environment	OTC, home environment	OTC, home environment	Same
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, ABS, Polyester	Silicone	**Different:** The subject and predicate devices have different patient contacting materials. These differences do not raise different questions of S&E.
Cap loading/delivery	Semen added to cap in applicator using a removable funnel. Cap delivered and deployed via applicator	Placed and deployed in vagina after intercourse	**Different:** The subject device is loaded with sperm before delivery, while the predicate is placed after intercourse. These differences do

			not raise different questions of S&E.
Human Sperm Survival Assay (HSSA) Conducted	Yes, ≥ 80% motility after 24-hour exposure to the Cervical cap, funnel, and semen collection cups	Yes, ≥ 80% motility after 2-hour exposure to the Conception Cup	**Different –** Testing assessing the compatibility of the sperm-contacting device components with semen are not the same. This difference between the subject and predicate device does not raise different questions of S&E.
Wear time	≤ 5 hours	≤ 1 hours	**Different:** The difference in wear-time between the subject and predicate device does not raise different questions of S&E.
Shelf-life	Shelf Life: 7 months	Shelf Life: 36 months	**Different -** The predicate device shelf-life is greater than the subject device. Differences in shelf-life duration do not raise different questions of S&E.
Reprocessing and Reuse	Single use	Use Life: 3 months Device is reprocessed between uses.	**Different –** The predicate device is reusable, while the subject device is single use only. These differences do not raise different questions of S&E
Dimensions	Cap Dimensions: Width (OD): 42.4 ± 0.5 mm Height: 45.8 ± 0.5 mm Applicator Dimensions: Outer diameter: 24.6 ± 0.5 mm Applicator length: 242.5 ± 0.5 mm Semen Collection Container Dimensions: Overall Width: 53.0 ± 1.0 mm	Cap Dimensions: OD: 1.27 ± 0.05 in Cap Depth: 0.85 ± 0.035 in Total length (with retrieval): 4.33 ± 0.05 in	**Different –** Differences in dimensions do not raise different questions of S&E.

	Overall Height: 63.0 ± 1.0 mm		
Cap Volume	13.0 mL	13.8 mL	Similar

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 compatibility testing methods, etc. do not raise different questions of safety and effectiveness as compared to the predicate device.

8. Summary of Non-Clinical Performance Testing

Biocompatibility:
Biocompatibility studies were performed in accordance with the 2023 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)

The results of testing demonstrate that the subject device is non-cytotoxic, non-irritating, and non-sensitizing.

Shelf Life:
A real-time shelf-life study was performed to verify that the Béa Applicator maintained its specifications over its entire 7-month shelf-life. Specifications assessed in support of device shelf-life include the following:

- Visual inspection to confirm the general integrity of the packaging and the legibility of the labeling
- Visual inspection for discoloration, clouding, cracking, peeling, and other visual defects
- Functional testing of cervical cap deployment
- The overall dimensions of the cervical cap (OD, height), the Applicator (OD, height), the semen collection container (OD, height)
- Hardness of the cervical cap (Shore A)
- Tear resistance of the cervical cap
- Compression force of the cervical cap
- Tensile strength of the cervical cap and string system
- Leakage assessment to ensure minimum volume of fluid is retained in cap
- HSSA
- Bioburden per USP <61> and USP <62> for non-sterile components (applicator, funnel, and cervical cap)

9. Summary of Clinical Performance Testing

A US-Based human factors validation study was comprised of the following assessments: Self-Selection, Label Comprehension, Simulated Use, and Actual Use Usability testing for the Béa

Applicator to support OTC at home use of the device. Individuals representing the US population participated in the HF validation testing, with literacy determined by Rapid Estimate of Adult Literacy in Medicine (REALM) assessment. This comprised of 68 self-selection participants, 15 label comprehension and simulated use participants, and 26 actual use participants.

The sponsor also conducted a supplemental study with the same protocol and included self-selection, label comprehension, simulated use, and actual use testing for individuals in the low literacy cohort. 23 participants were recruited with a REALM score of less than 45 in the HF validation test, and an additional 15 for the labeling comprehension to evaluate the revised labeling, four of whom were low literacy. Eleven of the new low REALM population participated in self-selection, four for label comprehension and simulated use, and five completed actual use.

The combined simulated use and labeling comprehension study was conducted to evaluate if the Béa Applicator (including its associated documentation) is as safe and effective as the predicate device for the intended use by the intended users in the intended use environments. The following knowledge tasks were evaluated as part of simulated use testing:

- When should this product be used?
- How many times can the product be used?
- How long can the Cervical Cap remain inside the vagina?
- In what instances should someone not use the product?
- If your skin gets irritated while using the product, what should you do?
- What should you do if the product becomes stuck inside the vagina?
- What should you check before using the product?
- How should you insert the device?
- How would you know that the applicator is all the way in?
- Can you have sexual activity while the cervical cap is inside you?

The actual use clinical study was conducted to evaluate the following three clinical end points.

- Can be positioned correctly with the Cervical Cap over the cervical os
- Can retain semen in the cervical cap
- Does not cause trauma/injury to the vagina

The study found that all subjects were able to successfully use the device with all above outcomes met, demonstrating simulated use and actual use respectively.

In conclusion, the clinical studies demonstrated that the intended use population across different health literacy levels was able to comprehend the Béa Applicator 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.

10. Conclusion

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