November 29, 2023

Mosie Baby
% Julie Engel
Principal Consultant
Parexel International
2520 Meridian Parkway, Suite 200
Durham, NC 27713

Re: K231203
Trade/Device Name: Mosie Baby Kit
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: QYZ
Dated: October 30, 2023
Received: October 30, 2023

Dear Julie Engel:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231203

Device Name
Mosie Baby Kit

Indications for Use *(Describe)*
The Mosie Baby Kit is indicated for over-the-counter home use, by individuals who have been unable to conceive through intercourse or choose not to conceive through intercourse, for semen collection and the delivery of semen or donor sperm to the vaginal canal. The Mosie Baby Kit should be used during the ovulatory phase of the menstrual cycle.

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.

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510(k) Summary

K231203 - Mosie Baby Kit

Date Prepared:	November 28, 2023
Submitter:	Mosie Baby
Submitter Contact Information:	Maureen Brown CEO and Co-Founder Mosie Baby 6448 East Highway 290 Suite F-109 Austin, TX 78723 +1 866 679 4511 info@mosiebaby.com
Submission Correspondent:	Trisha Eustaquio, PhD Vice President, Technical Parexel International 2520 Meridian Parkway Suite 200 Durham, NC 27713 +1 978 435 8549 trisha.eustaquio@parexel.com
Proprietary Name:	Mosie Baby Kit
Common Name:	At Home Intravaginal Insemination System
Classification:	Catheter, Assisted Reproduction (21 CFR 884.6110, Product Code QYZ)
Regulatory Class	II
Predicate Device:	Shepard Intrauterine Insemination Set (K172321) The predicate device has not been subject to a design-related recall.

Device Description Summary

The Mosie Baby Kit is an over-the-counter (OTC) device intended for intravaginal insemination (IVI) at home. The Mosie Baby Kit includes the following components:

- Two Mosie syringes
- Two Mosie collection cups
- Instructions for Use

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Each component is single-use only and supplied non-sterile. The collection cup is used to hold and contain the sperm and work in conjunction with the syringe when it is time to transfer the sperm into the syringe. The syringe is used to withdraw the semen from the collection cup and deploy the semen intravaginally. The syringe features a rounded front end with a slotted tip opening. The syringe has a rounded stopper that fits within the rounded end of the syringe to aid in sperm delivery from the syringe to the vagina. The syringe also contains flanges designed to aid in device handling during use.

Indications for Use

The Mosie Baby Kit is indicated for over-the-counter home use, by individuals who have been unable to conceive through intercourse or choose not to conceive through intercourse, for semen collection and the delivery of semen or donor sperm to the vaginal canal. The Mosie Baby Kit should be used during the ovulatory phase of the menstrual cycle.

Comparison of Intended Use and Technological Characteristics with the Predicate Device

The following table compares the Mosie Baby Kit to the predicate device.

Comparison Item	**Subject Device – K231203**	**Predicate Device – K172321**	**Comparison**
Manufacturer	Mosie Baby	Cook Incorporated	Not applicable
Trade Name	Mosie Baby Kit	Shepard Intrauterine Insemination Set	Not applicable
Indications for Use	The Mosie Baby Kit is indicated for over-the-counter home use, by individuals who have been unable to conceive through intercourse or choose not to conceive through intercourse, for semen collection and the delivery of semen or donor sperm to the vaginal canal. The Mosie Baby Kit should be used during the ovulatory phase of the menstrual cycle.	Intrauterine Insemination Catheters are used for the introduction of washed spermatozoa into the uterine cavity.	Different

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Comparison Item	Subject Device – K231203	Predicate Device – K172321	Comparison
Prescription or OTC	OTC	Rx	Different
Device Components	Syringe, cup	Catheter	Different
Insemination Procedure	Intravaginal insemination	Intrauterine insemination	Different
Material	Syringe: polycarbonate, silicone, ABS Cup: polystyrene	Polyethylene Stainless steel Silicone Polycarbonate	Different
Sterile	Non-sterile	Sterile	Different
Single Use	Yes	Yes	Same

The subject and predicate devices have differences in their indications for use statements, as the Mosie Baby Kit is for delivery of semen/sperm to the vagina, while the predicate device is for delivery of washed spermatozoa to the uterine cavity. In addition, the Mosie Baby Kit is for OTC home use while the predicate is a prescription use device for use in a clinical setting. The differences between the indications for use for the two devices do not represent a new intended use as both devices are intended to deliver sperm to the female reproductive tract as an aid to conception.

The subject and predicate devices have differences in technological characteristics, including device components, type of procedure, environment of use, materials, and sterility, as shown above. These differences do not raise different questions of safety or effectiveness.

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Non-Clinical and/or Clinical Tests Summary & Conclusions

Shelf Life

A shelf-life study was conducted on test articles that were aged under accelerated conditions, per ASTM F1980-21. Specifications assessed in support of the device shelf-life include the following, which are further described below:

- Bioburden
- Functional Testing
- Human Sperm Survival Assay (HSSA)

Bioburden Testing

Bioburden testing for the Mosie syringe and cup were performed in accordance with USP <61> and <62>. The test articles were assessed at baseline and the end of shelf-life and met the bioburden specifications for vaginal use in accordance with USP <1111>. The acceptance specifications for the Mosie Syringe and Mosie Cup are shown below:

- Total aerobic microbial count (TAMC) per USP <61>: $<10^2$ cfu/g
- Total yeast and mold count (TYMC) per USP <61>: $<10^1$ cfu/g
- Presence of Pathogens per USP <62>: Absence of *Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans*

Functional Testing

Functional testing on the Mosie syringe and collection cup was conducted at baseline and the end of shelf-life.

The tests for the Mosie syringe, developed based on ISO 7886-1:2017, include:

- Extraneous matter - general (clause 6.1),
- Barrel dimensions (clause 10.1),
- Barrel flanges (clause 10.2),
- Plunger stopper / plunger assembly design (clause 11.1),
- Freedom from liquid leakage past plunger stopper (clause 13.2),
- Force to operate the piston (clause 13.3), and
- Fit of plunger stopper / plunger in barrel (clause 13.4).

The tests for the Mosie collection cup include:

- Visual inspection, and
- Dimensional inspection.

Human Sperm Survival Assay (HSSA)

HSSA was conducted on the Mosie syringe and collection cup to demonstrate that the syringe and cup materials are not sperm-toxic. The HSSA was conducted on samples at baseline and the end of shelf-life.

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Syringes and collection cups were shown to meet the HSSA acceptance specification (≥80% of control motility at 24 hours) at all time points assessed.

Biocompatibility Testing

Biocompatibility testing 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" as follows:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Vaginal irritation per ISO 10993-23:2021

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

Clinical Performance Testing

Data from two clinical studies was used to support self-selection and labeling comprehension testing for the subject device, to support OTC home use.

Self-Selection Study (with Labeling Comprehension)

A labeling comprehension and self-selection study was conducted with the Mosie Baby Kit. The study assessed whether potential users could accurately determine if they should use the product or not based on labeling, and if potential users could understand the indications for use, contraindications, and what the product is not intended to treat. The study consisted of thirty-two (32) participants: fifteen (15) contraindicated female participants and seventeen (17) non-contraindicated female participants. All participants varied in age, occupation, ethnicity, highest level of completed education, and English health literacy level [as determined by the Rapid Estimate of Adult Literacy in Medicine (REALM) test]. Additionally, participants were representative of the intended user in the United States, as all participants who were not contraindicated (intended users) reported that they were attempting to conceive and had varying degree of comfort/experience in using and inserting devices into the vagina.

All participants were able to identify the following information on the labeling:

- Who the kit is indicated/intended for,
- Whether it is acceptable for them to use the product (and why or why not),
- What difficulty they had, if any in determining whether it was acceptable for them to use the product,
- Who should not use the kit, and
- What the product acknowledges that it does not do.

Human Factors Validation Study (with Labeling Comprehension)

A human factors validation study was performed with the Mosie Baby Kit. The study validated that potential users could successfully use the Mosie Baby Kit using only the information in the device labeling (package label and Instructions for Use) and that performance of critical tasks would not result in use errors or harm to the patient; and that use-related risks for the final/finished product were eliminated or mitigated. A total of thirty participants were enrolled: fifteen participants who self-administered and fifteen

participants who administered to a female recipient were enrolled. All participants varied in age, gender, occupation, ethnicity, highest level of completed education, and English health literacy level [as determined by the Rapid Estimate of Adult Literacy in Medicine (REALM) test]. Additionally, participants were representative of the intended user in the United States, as all participants reported that they were attempting to conceive and had varying degree of comfort/experience in using and inserting devices into the vagina.

Participants self-familiarized with the Mosie Baby Kit and Instructions for Use (IFU) and were then asked to perform the procedure unaided. After completing the simulated procedure, participants were asked about their experience and were asked questions about information in the IFU related to the following:

- When to use the kit,
- How often to use the kit,
- When to contact a physician,
- What to collect the semen sample in,
- Storage of the semen sample (if needed),
- How long the semen sample can be stored (if needed),
- What not to do after filling the syringe until the syringe is fully inserted in the vagina,
- What the female recipient should do after the insemination procedure,
- Disposing of the used product, and
- When to use the second syringe and cup.

These questions included warnings and precautions provided in the device labeling, with the exception of who should not use the device, as this was addressed in the self-selection study discussed above. All questions were answered correctly by at least 90% of participants, and none of the participants stated difficulty understanding the answers to any of the questions.

In conclusion, self-selection and label comprehension were demonstrated across both studies to support OTC use of the device and substantial equivalence to the predicate device. The study population also reported demographic information representative of the US population and successfully completed all elements of the studies.

Conclusion

The results of the performance testing support a determination of substantial equivalence of the subject device to the predicate devices, and do not raise any new questions of safety or effectiveness.