September 22, 2023

Femasys, Inc.
Christine Thomas
SVP, Regulatory & Clinical Affairs
3950 Johns Creek Court, Suite 100
Suwanee, GA 30024

Re: K231730
Trade/Device Name: FemaSeed Intratubal Insemination
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: August 18, 2023
Received: August 22, 2023

Dear Christine Thomas:

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,

Monica D. Garcia -S

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)*
K231730

Device Name
FemaSeed Intratubal Insemination

Indications for Use *(Describe)*
The FemaSeed Intratubal Insemination is intended to introduce washed sperm or in vitro fertilized (IVF) embryos into the uterine ostium via ultrasound guidance

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 – K231730

I. SUBMITTER

Applicant: Femasys Inc.
Applicant Address: 3950 Johns Creek Court, Suite 100
Suwanee, GA 30024

Phone: +770-500-3910 x137
Email: CThomas@femasys.com
Contact Person: Christine Thomas
Sr. VP, Regulatory & Clinical Affairs

Date Prepared: September 21, 2023

II. DEVICE

Trade Name: FemaSeed Intratubal Insemination
Common Name: Transfer Catheter
Regulation Name: Assisted Reproduction Catheters
Regulation Number: 21 CFR 884.6110
Regulatory Class: II
Product Code: MQF (Catheter, Assisted Reproduction)

III. PREDICATE DEVICE

K983591 Intratubal Transfer Sets, currently legally marketed as Echosight Jansen-Anderson Intratubal Transfer Set.

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

IV. DEVICE DESCRIPTION

The FemaSeed Intratubal Insemination consists of polymer curved transfer catheter with balloon, polymer guide catheter and separate balloon inflation syringe. The balloon inflation syringe is a 3 mL syringe fitted with clips that allow for the piston to lock in place to maintain balloon inflation. When the clips are pinched, the piston releases, deflating the balloon. The device is intended to deliver washed sperm or in vitro fertilized embryos into the uterine ostium via ultrasound guidance by a licensed healthcare provider specifically trained in women's health.

Prior to insertion, the slider is moved back until the curved transfer catheter is fully retracted and contained within guide catheter. The preassembled guide catheter is then passed transvaginally through the cervix to the fundus, under ultrasound guidance.

Once in position, the preloaded transfer catheter is advanced approximately 2 cm into the uterine ostium and the balloon is inflated with the provided syringe. The balloon location in the uterine ostium is confirmed using ultrasound. The samples are then instilled into the uterine ostium of the fallopian tube, followed by deflating the balloon and discarding the device. The recommended volume for loading washed sperm should not exceed 1 mL and 50-100 µL when loading embryos.

V. INDICATIONS FOR USE

The FemaSeed Intratubal Insemination is intended to introduce washed sperm or in vitro fertilized (IVF) embryos into the uterine ostium via ultrasound guidance.

VI. COMPARISON OF THE INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICES

The following table compares the FemaSeed Intratubal Insemination Transfer Catheters to the predicate device.

Table 1. Intended use and technological characteristics comparison.

Comparison Item	**Subject Device – K231730**	**Predicate Device – K983591**	**Comparison**
Classification	21 CFR 884.6110	21 CFR 884.6110	Same
Product code	MQF	MQF	Same
Indications for Use	The FemaSeed Intratubal Insemination is intended to introduce washed sperm or in vitro fertilized (IVF) embryos into the uterine ostium via ultrasound guidance.	The intratubal transfer sets are used to inject either sperm, gametes or embryos into the uterine ostium of the fallopian tube via ultrasound guidance. The device is sterile and intended for one time use.	Similar
Design Features	The FemaSeed Intratubal Insemination consists of a polymer curved transfer catheter, polymer guide catheter and a separate balloon	The Intratubal Transfer Set consists of a polymer curved guide catheter, stainless steel, malleable obturator, stainless	Different

Comparison Item	Subject Device – K231730	Predicate Device – K983591	Comparison
	inflation syringe. The transfer catheter includes an inflatable balloon.	steel wire guide and a polymer transfer catheter.	
Catheter Assembly	Preassembled catheters, separate syringe	Separate catheters, separate stainless-steel obturator	Different
Outer and Inner Diameters	Guide catheter 3.8 mm Transfer catheter 1.5 mm There are two (2) lumens of the transfer catheter: • Specimen lumen ID 0.036” +0.000 / -0.003” • Balloon inflation lumen ID 0.010” +0.000 / -0.002” The dimension of the balloon when inflated is a minimum of 34F	Guide catheter 1.9 mm Transfer catheter 1 mm	Different
Materials	Polymer (Pebax/Pellethane)	Polymer Stainless steel	Different
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Single Use	Yes	Yes	Same
Shelf Life	6-months	36-months	Different
Mouse Embryo Assay	2-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 72 hours.	Not available publicly	Not applicable
Endotoxin	< 20 EU/device	Not available publicly	Not applicable
HSSA	≥80% of control motility at 24 hours following 30-minute exposure.	Not available publicly	Not applicable

The subject and predicate devices have similar indications for use statements and have the same intended use. As shown in the table above, the subject and predicate device have some technological characteristics that are the same or similar. However, there are differences in design, materials and shelf-life. These differences do not raise different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The following studies have been performed to support substantial equivalence to the predicate device:

- Ethylene Oxide Sterilization Validation testing per:
  - ISO 11135-1:2014
  - AAMI TIR 28:2016
  - ISO 10993-7: 2008

- Package Integrity testing:
  - Visual inspection
  - Bubble Leak test per ASTM F2096-11
  - Seal Strength testing per ASTM F88/ F88M-15

- Transportation Simulation testing per ASTM D4169-14

- Biocompatibility studies conducted 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."* Testing included the following assessments:
  - Cytotoxicity per ISO 10993-5: 2009
  - Sensitization ISO 10993-10: 2010
  - Irritation per ISO 10993-10: 2010

  Testing showed the device material to be non-cytotoxic, non-sensitizing, and non-irritating.

- Endotoxin testing per USP <85> and AAMI/ANSI ST72:2019
  - Specification: <20 EU/device

- Bench performance studies before and after accelerated aging to the equivalent of 6-months of real-time aging in accordance with ASTM F1980-16 demonstrated that all predetermined acceptance criteria were met in the following tests:
  - Appearance
  - Dimensional analysis
  - Mechanical performance
  - Device interface compatibility
  - Balloon integrity, maximum burst pressure analysis, maximum cycles for stop

lock clips to maintain balloon inflation
- Maximum extension force for transfer and guide catheters
- Depth of insertion and transfer catheter advancement testing
- Aspiration and delivery testing
- Minimize lost specimen during aspiration and delivery
- Indicate when transfer catheter is fully advanced or retracted
- Guide catheter insertion without kinking and minimize patient discomfort or risk of injury
- Human Sperm Survival Assay (HSSA) demonstrating ≥80% of control motility at 24 hours following 30-minute exposure.
- Mouse Embryo Assay (MEA) per the 2021 FDA guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices:* Specification - 2-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 72 hours.

VIII. CONCLUSIONS

The results of the testing described above demonstrate that the FemaSeed Intratubal Insemination transfer catheters are as safe and effective as the predicate device and supports a determination of substantial equivalence.