December 15, 2025

Femasys, Inc.
Christine Thomas
Chief Regulatory and Clinical Officer
3950 Johns Creek Court, Suite 100
Cumming, GA 30041

Re: K253403
Trade/Device Name: FemVue® Controlled Saline-Air Device (FSA-300)
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: September 29, 2025
Received: September 30, 2025

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 (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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253403

Please provide the device trade name(s).

FemVue® Controlled Saline-Air Device (FSA-300)

Please provide your Indications for Use below.

FemVue® Controlled Saline-Air Device is intended to instill a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary – K253403

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 Chief Regulatory, Quality and Clinical
Date Prepared:	December 3, 2025

II. DEVICE

Trade Name:	FemVue® Controlled Saline-Air Device
Common Name:	Contrast media syringe
Regulation Name:	Obstetric-gynecologic specialized manual instrument
Regulation Number:	21 CFR 884.4530
Regulatory Class:	II
Product Code:	LKF (Cannula, Manipulator/Injector, Uterine)

III. PREDICATE DEVICE

FemChec® Controlled Saline-Air Device (K241693), manufactured by Femasys Inc.

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

IV. DEVICE DESCRIPTION

The FemVue® Controlled Saline-Air Device is a sterile dual-barrel contrast media syringe that is connected to an intrauterine catheter to instill saline-air contrast medium as part of a sono-hysterosalpingogram (Sono-HSG) procedure. Ultrasound of the fallopian tubes can be performed with or without assessment of the uterine cavity.

The device operates by retraction of the plunger, which simultaneously fills the two syringes in the device with either air or saline. The device is then connected to a compatible uterine catheter and when the plunger is depressed, a consistent stream of saline and air is delivered into the uterus and fallopian tubes. The device is provided sterile via ethylene oxide (EO) sterilization and is intended for single-use.

V. INDICATIONS FOR USE

FemVue® Controlled Saline-Air Device is intended to instill a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).

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

The indications for use and key technological characteristics of the subject and predicate device are compared in the table below.

Table 1. Indications for use and technological characteristics comparison.

Comparison Item	FemVue® Controlled Saline-Air Device Subject Device	FemChec® Controlled Saline-Air Device Predicate Device	
Submission Number	K253403	K241693	N/A
Regulation	21 CFR 884.4530	21 CFR 884.4530	**Same**
Device Classification	Class II	Class II	**Same**
Product Code	LKF	LKF	**Same**
Product Code Description	Cannula, Manipulator/Injector, Uterine	Cannula, Manipulator/Injector, Uterine	**Same**
Regulation Name	Obstetric-gynecologic specialized manual instrument	Obstetric-gynecologic specialized manual instrument	**Same**
Indications for Use	FemVue® Controlled Saline-Air Device is intended to instill a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).	The FemChec® is intended to instill a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).	**Same** apart from Trade Name
Design Feature	Dual-barrel contrast media syringe that can be connected to an intrauterine catheter.	Dual-barrel contrast media syringe that can be connected to an intrauterine catheter.	**Same**
Prescription Only	Yes	Yes	**Same**
Catheter Luer Connection	Spin Luer	Spin Luer	**Same**
Plunger Control Feature	Ratcheted Plunger Design	Ratcheted Plunger Design	**Same**

Contrast Viewing Window	Contrast bubbles viewed through neck of luer	Contrast bubbles viewed through window in device	**Different**: The different viewing location of the contrast bubbles do not raise different questions of safety and effectiveness.

Both the subject device and predicate device are a dual-barrel contrast media syringe intended to instill a consistent alternating pattern of saline and air as a continuous stream of contrast media through a connected intrauterine catheter into the uterus and fallopian tubes for performance of sono-hysterosalpingogram (Sono HSG) procedure. Both devices designed and manufactured by Femasys Inc. are of the same materials and are fundamental design, are single use only and sterilized via ethylene oxide (EO).

The subject does not have a viewing window, unlike the predicate device, but has the same design as the FDA cleared FemVue (K110288) and FemVue MINI (K242002) devices, with the same intended use. The difference does 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. Due to the similar device design and packaging, test methods and data from the predicate device are leveraged to support the subject device:

- Ethylene Oxide Sterilization Validation testing per:
  - ISO 11135:2014
  - 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-23
- Transportation Simulation testing per ASTM D4169-22
- Biocompatibility studies conducted 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."* For devices in indirect contact with mucosal tissues. Testing included the following assessments:
  - Cytotoxicity per ISO 10993-5: 2009
  - Sensitization per ISO 10993-10: 2021
  - Irritation per ISO 10993-23: 2021

  Testing showed the device material to be non-cytotoxic, non-sensitizing, and non- irritating.
- Bench performance studies before and after accelerated aging to the equivalent of 4.6 years

of real-time aging in accordance with ASTM F1980-21 demonstrated that all predetermined acceptance criteria were met in the following tests:

- Visual Inspection
- Functional/Cycle Testing
- Saline-Air Quantification

VIII. CONCLUSIONS

The results of the testing described above demonstrate that the FemVue Controlled Saline-Air Device is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.