



November 22, 2024

Femasys Inc.
Carrie Engleman
Associate Director of Regulatory
3950 Johns Creek Ct.
Suite 100
Suwanee, Georgia 30024

Re: K242002
Trade/Device Name: FemVue MINI Saline-Air Device
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: July 9, 2024
Received: July 9, 2024

Dear Carrie Engleman:

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

Submission Number (if known)

K242002

Device Name

FemVue MINI Saline-Air Device

Indications for Use (Describe)

FemVue MINI 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).

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
PRASStaff@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 – K242002

I. SUBMITTER

Applicant: Femasys Inc.

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

Contact Primary: Carrie Engleman
Associate Director, Regulatory
Phone: 770-500-3910 x 138
Email: Cengleman@femasys.com

Contact Secondary: Christine Thomas
Senior VP, Regulatory and Clinical
Phone: 770-500-3910 x 137
Email: Cthomas@femasys.com

Date Prepared: November 20, 2024

II. DEVICE

Trade Name: FemVue® MINI 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

FemVue® Saline-Air Device (K110288), manufactured by Femasys Inc.

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

IV. DEVICE DESCRIPTION

FemVue® MINI is a dual-barrel contrast media syringe that can be connected to an intrauterine catheter for controlled delivery of saline-air contrast media during sono-hysterosalpingogram (Sono HSG) procedures. Sono HSG consists of an ultrasound evaluation of the fallopian tubes 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 EO sterilization and is intended for single-use.

V. INDICATIONS FOR USE

FemVue® MINI 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 intended use and key technological characteristics of the subject and predicate device are compared in the table below.

Table 1. Intended use and technological characteristics comparison.

Comparison Item	FemVue® MINI Saline-Air Device Subject Device	FemVue® Saline-Air Device Predicate Device	Comparison
510(k)	K242002	K110288	N/A
Regulation Number	884.4530	884.4530	Same
Device Class	Class II	Class II	Same
Product Code	LKF	LKF	Same
Device Classification Name	Cannula, Manipulator/Injector, Uterine	Cannula, Manipulator/Injector, Uterine	Same
Regulation Description	Obstetric-gynecologic specialized manual instrument	Obstetric-gynecologic specialized manual instrument	Same
Regulation Medical Specialty	Obstetrics/Gynecology	Obstetrics/Gynecology	Same
Indications for Use	FemVue MINI 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 FemVue Saline-Air Device instills 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
Design Features	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
Principle of Operation	Sterile dual-barrel contrast media syringe that is connected to an intrauterine catheter to instill saline-air contrast medium as part of a sono-	Sterile dual-barrel contrast media syringe that is connected to an intrauterine catheter to instill saline-air contrast medium as part of a sono-	Same

Comparison Item	FemVue® MINI Saline-Air Device Subject Device	FemVue® Saline-Air Device Predicate Device	Comparison
	hysterosalpingogram (Sono HSG) procedure.	hysterosalpingogram (Sono HSG) procedure.	
Prescription Only	Yes	Yes	Same
Target Patient Population	Patient undergoing Sono HSG procedure.	Patient undergoing Sono HSG procedure.	Same
Shelf Life	12 months	60 months	Different. The differences do not raise different questions of safety and effectiveness.
Syringe	5 mL	10 mL	Different. The different size of the syringes does not raise different questions of safety and effectiveness.

The subject and predicate device have the same intended use – 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. The subject and predicate device have the same principle of operation (dual-barrel syringe device that delivers saline and air contrast through an intrauterine catheter). However, minor modifications have been made to the device dimensions and the materials to reduce the overall size of the FemVue MINI device in comparison to the predicate device. 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 11135:2014
 - 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
 - Seal Visual Inspection per ASTM F1886/F1886-16
- 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"*. Testing included the following assessments:
 - Cytotoxicity per ISO 10993-5: 2009
 - Sensitization ISO 10993-10: 2021
 - Irritation per ISO 10993-10: 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 12-months of real-time aging in accordance with ASTM F1980-16 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 demonstrate that the FemVue MINI Saline-Air Device are as safe and effective as the predicate device and supports a determination of substantial equivalence.