May 30, 2025

FertiPro NV
℅ Sarah Robbins
Senior Quality Manager, Consultant
Rock Quality Systems
1155 Mount Vernon Hwy Suite 800,
Dunwoody, GA 30338 USA

Re: K242640
Trade/Device Name: FertiCult Flushing medium; FertiCult Flushing medium with phenol red and gentamicin
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: March 5, 2024
Received: September 3, 2024

Dear Sarah Robbins:

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

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)*
K242640

Device Name
FertiCult Flushing medium; FertiCult Flushing medium with phenol red and gentamicin

Indications for Use *(Describe)*

FertiCult™ Flushing medium are intended for in vitro procedures involving human gametes (sperm and oocytes), including washing of gametes, sperm swim-up procedures, intra-uterine insemination (IUI) of the spermatozoa and sperm injection during intracytoplasmic sperm injection (ICSI). FertiCult™ Flushing medium can also be used human embryo washing and holding, and for embryo transfer (ET) in the uterine cavity. The medium is NOT intended for oocyte pick-up and follicle flushing. FertiCult Flushing medium is used during assisted reproductive Technology (ART) procedures of patients and couples undergoing infertility treatments.

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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*"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**
**K242640**

## I. SUBMITTER


| | |
|---|---|
| Applicant: | FertiPro NV |
| Address: | Industriepark Noord 32, 8730 Beemem Belgium |
| Phone: | (+32)50791805 |
| Email: | ra.@fertiPro.com |
| Contact Person: | Liesbeth Faes, Management Representative FertiPro NV |
| Email: | liesbeth@fertipro.com |


Date Prepared: May 28, 2025

## II. DEVICE

| | |
|---|---|
| Trade Name: | FertiCult Flushing medium; FertiCult Flushing medium with phenol red and gentamicin |
| Common Name: | Assisted Reproduction Media |
| Regulation Name: | Reproductive Media and Supplements |
| Regulation Number: | 884.6180 |
| Product Code: | MQL (Media, Reproductive) |
| Regulatory Class: | II |

## III. PREDICATE DEVICE

K983586 - HTF Medium, Modified HTF Medium-HEPES, HTF Powder (without antibiotics), Modified HTF Powder-HEPES (without antibiotics), Modified HTF Powder-HEPES from Irvine Scientific Sales Co., Inc.

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

## IV. DEVICE DESCRIPTION

FertiCult Flushing medium and FertiCult Flushing medium with phenol red and gentamicin intended for in vitro procedures involving human gametes (sperm and oocytes), including washing of gametes, sperm swim-up procedures, intra-uterine insemination (IUI) of the spermatozoa and sperm injection during intracytoplasmic sperm injection (ICSI). FertiCult Flushing media can also be used for human embryo washing and holding, and for embryo transfer (ET) in the uterine cavity.

The base formulation contains Water, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Sulphate Heptahydrate, Sodium Dihydrogen Phosphate Dihydrate, Sodium Pyruvate, Glucose Monohydrate, Sodium Lactate, Sodium hydrogen carbonate, HEPES, Human Serum Albumin.

A FertiCult Flushing media variant contains Phenol red and
Gentamicin.

The products can be used up to 7 days after opening, when sterile conditions are maintained, and the products are stored at 2-8°C.

## V. INDICATIONS FOR USE

FertiCult™ Flushing medium are intended for in vitro procedures involving human gametes (sperm and oocytes), including washing of gametes, sperm swim-up procedures, intra-uterine insemination (IUI) of the spermatozoa and sperm injection during intracytoplasmic sperm injection (ICSI). FertiCult™ Flushing medium can also be used human embryo washing and holding, and for embryo transfer (ET) in the uterine cavity. The medium is NOT intended for oocyte pick-up and follicle flushing. FertiCult Flushing medium is used during assisted reproductive Technology (ART) procedures of patients and couples undergoing infertility treatments.

## VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the intended use and technological features of the subject and predicate devices are described in the table below:

| Comparison Item | K242640<br>Subject Device | K983586<br>Predicate Device | Comparison |
|---|---|---|---|
| Indications for Use | FertiCult™ Flushing medium are intended for in vitro procedures involving human gametes (sperm and oocytes), including washing of gametes, sperm swim-up procedures, intra-uterine insemination (IUI) of the spermatozoa and sperm injection during intracytoplasmic sperm injection | HTF and Modified HTF are intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos. Specifically, HTF is intended for use as a culture medium for the embryo after fertilization, when used with an | There are differences in the wording of the indications for use statements for the subject and predicate device; however, |

| Comparison Item | K242640 Subject Device | K983586 Predicate Device | Comparison |
|---|---|---|---|
| | (ICSI). FertiCult™ Flushing medium can also be used human embryo washing and holding, and for embryo transfer (ET) in the uterine cavity. The medium is NOT intended for oocyte pick-up and follicle flushing. FertiCult Flushing medium is used during assisted reproductive Technology (ART) procedures of patients and couples undergoing infertility treatments. | incubator, and as a medium to support in vitro fertilization. Modified HTF is intended for use as a sperm-processing medium in washing procedures, as an oocyte retrieval medium, for transport of the embryo, and as a support medium for implantation of the embryo. Both HTF and Modified HTF are intended to simulate the substances found in the human, female reproductive system. | the indications for use statements for the predicate device are similar in intended use for sperm-processing, sperm, oocyte, and embryo manipulation, embryo transfer. |
| Conditions for Use | Prescription Use Only | Prescription Use Only | **Same** |
| Composition | Water<br>Sodium Chloride<br>Potassium Chloride<br>Calcium Chloride Dihydrate<br>Magnesium Sulphate Heptahydrate<br>Sodium Dihydrogen Phosphate Dihydrate<br>Sodium Pyruvate<br>Glucose Monohydrate<br>Sodium Lactate<br>Sodium hydrogen carbonate<br>HEPES<br>Human Serum Albumin<br>Phenol red<br>Gentamicin | Water<br>Sodium-D, L-lactate<br>Sodium chloride<br>Potassium chloride<br>Glucose anhydrous<br>Magnesium sulfate, anhydrous<br>Potassium phosphate, monobasic<br>Pyruvic acid, sodium salt<br>Calcium chloride<br>HEPES ½ sodium salt<br>HEPES sodium salt<br>Sodium hydrogen carbonate<br>Hydrogen chloride | **Different:** The subject device and predicate devices have differences in media formulation. These differences in composition do not raise different questions of safety and effectiveness (S&E). |
| pH | 7.3-7.9 | 7.2-7.4 | **Different:** The differences in pH |

| Comparison Item | K242640 Subject Device | K983586 Predicate Device | Comparison |
|---|---|---|---|
| | | | specifications do not raise different questions of S&E. |
| Osmolality (mOsm/kg) | 270-290 mOsmol/kg | Not available publicly | **Different:** The differences in osmolality specifications do not raise different questions of S&E. |
| Bacterial Endotoxin | <0.25 EU/mL | Not available publicly | **Different:** The differences in endotoxin specifications do not raise different questions of S&E. |
| Mouse Embryo Assay | One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to test medium | Not available publicly | **Different:** The differences in MEA specifications do not raise different questions of S&E. |
| Sterilization Method | Aseptic Filtration<br>Vials are sterilized via radiation and moist heat | Not available publicly | **Different:** The differences in sterilization do not raise |

| Comparison Item | K242640 Subject Device | K983586 Predicate Device | Comparison |
|---|---|---|---|
| | | | different questions of S&E. |
| Shelf-Life | 18 months for medium in glass and 6 months for PETG bottles | Not available publicly | **Different:** The differences in shelf-life specifications do not raise different questions of S&E. |

As shown in the table above, there are differences in the indications for use statements and technological characteristics of the subject and predicate devices. However, as stated in the table, the differences in indications for use do not represent a new intended use and the differences in technological characteristics do not raise different questions of safety and effectiveness.

## VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following studies have been conducted in support of the substantial equivalence of the subject device to the predicate device.

- Aseptic filtration and aseptic filling validation, per ISO 13408-1:2023, Aseptic processing of health care products – Part 1: General requirements and ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration.
    - For filter challenge test per ISO 13408-2, the solutions used for testing did not contain antimicrobials (gentamicin was excluded from subject media formulation) and were representative of worst-case production conditions.
- PETG bottles radiation sterilization, per ISO 11137-1:2006 (including: Amendment 1 (2013) and Amendment 2 (2018)) Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2:2013 - Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]. Glass bottles sterilized per ISO 17665-1:2006 Sterilization of

health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

- Shelf-life testing was conducted to support a shelf-life of 18 months for media in glass bottles and 6 months for media in PETG bottles through demonstration that the product specifications (shown below) were met at time 0 and after real time aging (at 20- 25°C for FertiCult Flushing medium and 2-8°C for FertiCult Flushing medium with phenol red and gentamicin):
  - Appearance: All of the solutions should be without precipitates
  - pH per USP <791>: 7.3-7.9
  - Osmolality per USP <785>: 270-290 mOsmol/kg
  - Sterility per USP <71>: No microbial growth
  - Bacterial endotoxin per USP <85>: < 0.25 EU/mL
  - MEA per the 2021 FDA guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices*:
    - One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to test medium
- Transportation testing per ASTM D4169-22 (DC 13) and cap/seal leak testing using a method (dye immersion) equivalent to USP <1207.2> on transportation-conditioned devices.
- In-use testing to support the stability after bottle opening to ensure that product specifications (as noted in shelf-life above) are met seven days after opening of the bottles.
- Biocompatibility testing was conducted as the subject media is considered a device that contacts tissue with a limited (< 24 hours) contact duration as they can have direct contact with the patient (mother) during use in IUI and embryo transfer procedures Testing was conducted on FertiCult Flushing Media with phenol red and gentamicin (worst-case) 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)
  - Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2021)
  - Vaginal Irritation (ISO 10993-23: 2021)

  The results of the testing conducted support the biocompatibility of the patient contacting subject devices.

## VIII. CONCLUSION

The results of the performance testing described above demonstrate that FertiCult Flushing medium; FertiCult Flushing medium with phenol red and gentamicin is as safe and effective as the predicate device and supports a determination of substantial equivalence.