



May 14, 2021

Vitrolife Sweden AB  
Sarah Hood Hagberg  
Regulatory Affairs Manager  
Gustaf Werners gata 2  
Västra Frölunda, 42132  
Sweden

Re: K202862  
Trade/Device Name: Gx-IVF™, Gx-TL™, Gx-MOPST™ PLUS  
Regulation Number: 21 CFR§ 884.6180  
Regulation Name: Reproductive Media and Supplements  
Regulatory Class: II  
Product Code: MQL  
Dated: April 6, 2021  
Received: April 8, 2021

Dear Sarah Hood Hagberg:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

510(k) Number (if known)  
K202862

Device Name  
Gx-IVF™, Gx-TL™, Gx-MOPST™ PLUS

### Indications for Use (Describe)

Gx-IVF™ medium is intended for preparation and handling of gametes, for in vitro fertilisation and intrauterine insemination.

Gx-TL™ medium is intended for culture of embryos from fertilisation to the blastocyst stage and for embryo transfer.

Gx-MOPST™ PLUS medium is intended for handling and manipulating oocytes and embryos in ambient atmosphere.

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.

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## 510(k) Summary – K202862

### 1. Submitter Information

**Submitted by:** Vitrolife Sweden AB  
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**2. Date Prepared:** May 11, 2021

### 3. Device Identification

**Trade Name:** G<sub>x</sub>-IVF™, G<sub>x</sub>-TL™, G<sub>x</sub>-MOPST™ PLUS  
**Common Name:** IVF handling medium, embryo culture medium, IVF transfer medium  
**Regulatory Class:** Class II  
**Regulation Number:** 21 CFR 884.6180  
**Regulation Name:** Reproductive Media and Supplements  
**Product Code:** MQL (Media, Reproductive)

**4. Predicate Device(s):** G-IVF™ PLUS (K081116) manufactured by Vitrolife Sweden AB  
G-TL™ (K133568) manufactured by Vitrolife Sweden AB  
G-MOPST™ PLUS (K081115) manufactured by Vitrolife Sweden AB

The predicate devices have not been subject to a design related recall.

## 5. Device Description

The subject devices are culture and handling media consisting of physiological salts, energy substrates, amino acids, buffering agents, nutrients supplements, antioxidants, gentamicin and human serum albumin. These devices have different applications in Assisted Reproduction Technology (ART) procedures handled by IVF professionals, as follows:

- Gx-IVF™ medium is intended for preparation and handling of gametes, for in vitro fertilisation and intrauterine insemination.
- Gx-TL™ medium is intended for culture of embryos from fertilisation to the blastocyst stage and for embryo transfer.
- Gx-MOPS™ PLUS medium is intended for handling and manipulating oocytes and embryos in ambient atmosphere.

The media are aseptically filtered into gamma sterilised PETG bottles with HDPE closure and a tamper evident seal and tested for pH, osmolality, embryo toxicity, endotoxins, and sterility.

## 6. Indications for Use

Device	Indications for Use
Gx-IVF™	Gx-IVF™ medium is intended for preparation and handling of gametes, for in vitro fertilisation and intrauterine insemination.
Gx-TL™	Gx-TL™ medium is intended for culture of embryos from fertilisation to the blastocyst stage and for embryo transfer.
Gx-MOPS™ PLUS	Gx-MOPS™ PLUS medium is intended for handling and manipulating oocytes and embryos in ambient atmosphere.

## 7. Comparison of intended use and technological characteristics of subject and predicate devices

Device	Subject Device	Predicate Device (K081116)
<b>Trade name</b>	Gx-IVF™	G-IVF™ PLUS
<b>Indications for Use</b>	Gx-IVF™ medium is intended for preparation and handling of gametes, for in vitro fertilisation and intrauterine insemination.	Medium for preparation and handling of gametes, for in vitro fertilization.
<b>Composition</b>		
Antibiotics	Gentamicin	Gentamicin
Protein	Human Serum Albumin	Human Serum Albumin
Amino acids	YES	YES
Glucose	YES	YES
Physiological salts	YES	YES
Buffer	Sodium bicarbonate	Sodium bicarbonate
<b>Product and performance specification</b>		
pH	7.30 ± 0.10	7.30 ± 0.10
Osmolality (mOsm/kg)	265 ± 5	262 ± 5
Bacterial endotoxin (LAL assay) [IU or EU/mL]	< 0.25	< 0.25
Sterility	No evidence of microbial growth	SAL 10 <sup>-3</sup>
Mouse Embryo Assay (MEA)	1-cell: ≥ 80% embryos developed to expanded blastocyst at 96 hours	1-cell MEA % Expanded blastocyst on day 5: ≥ 80
Sterilization method	Aseptic filtration	Aseptic filtration
Storage conditions	Store dark at +2 to +8°C	Store dark at +2 to +8°C
Bottle	Nalgene PETG bottle with HDPE closure and tamper evident seal	Nalgene PETG bottle with HDPE closure and tamper evident seal
<p>The subject and predicate devices have similar Indications for Use and have the same intended use, as both the subject device and the predicate device are intended for use in ART procedures.</p> <p>The subject and predicate device have different technological features, including different ingredients and specifications. The different technological characteristics, including composition and specifications, do not raise different questions of safety and effectiveness.</p>		
Device	Subject Device	Predicate device (K133568)
<b>Trade name</b>	Gx-TL™	G-TL™
<b>Indications for Use</b>	Gx-TL™ medium is intended for culture of embryos from fertilisation to the blastocyst	Medium for culture of embryos from fertilisation to the blastocyst stage

	stage and for embryo transfer.	
<b>Composition</b>		
Antibiotics	Gentamicin	Gentamicin
Protein	Human Serum Albumin	Human Serum Albumin
Amino acids	Yes	Yes
Glucose	Yes	Yes
Hyaluronan	Yes	Yes
Physiological salts	Yes	Yes
Buffer	Sodium bicarbonate	Sodium bicarbonate
<b>Product and performance specification</b>		
pH	7.27 ± 0.07	7.30 ± 0.10
Osmolality (mOsm/kg)	265 ± 5	270 ± 5
Bacterial endotoxin (LAL assay) [IU or EU/mL]	< 0.25	< 0.25
Sterility	No evidence of microbial growth	SAL 10 <sup>-3</sup>
Mouse Embryo Assay (MEA)	1-cell: ≥ 80% embryos developed to expanded blastocyst at 96 hours	1-cell MEA % Expanded blastocyst within 96 hours: ≥ 80
Sterilization method	Aseptic filtration	Aseptic filtration
Storage conditions	Store dark at +2 to +8°C	Store dark at +2 to +8°C
Bottle	Nalgene PETG bottle with HDPE closure and tamper evident seal	Nalgene PETG bottle with HDPE closure and tamper evident seal
<p>The subject and predicate device have similar Indications for Use and the same intended use, as both the subject device and the predicate device are intended for use in ART procedures. The subject and predicate device have different technological features, including different ingredients and specifications. The different technological characteristics, including composition and specifications, do not raise different questions of safety and effectiveness.</p>		

<b>Device</b>	<b>Subject Device</b>	<b>Predicate device (K081115)</b>
<b>Trade name</b>	Gx-MOPST <sup>TM</sup> PLUS	G-MOPST <sup>TM</sup> PLUS
<b>Indications for Use</b>	Gx-MOPST <sup>TM</sup> PLUS medium is intended for handling and manipulating oocytes and embryos in ambient atmosphere	Medium for handling and manipulating oocytes and embryos in ambient atmosphere
<b>Composition</b>		
Antibiotics	Gentamicin	Gentamicin
Protein	Human Serum Albumin	Human Serum Albumin
Amino acids	Yes	Yes
Glucose	Yes	Yes
Physiological salts	Yes	Yes
Buffer	MOPS	MOPS
<b>Product and performance specification</b>		
pH	7.27 ± 0.07	7.27 ± 0.07
Osmolality (mOsm/kg)	265 ± 5	261 ± 5

Bacterial endotoxin (LAL assay) [IU or EU/mL]	< 0.25	< 0.25
Sterility	No evidence of microbial growth	SAL 10 <sup>-3</sup>
Mouse Embryo Assay (MEA)	1-cell: ≥ 80% embryos developed to expanded blastocyst at 96 hours	1-cell MEA % Expanded blastocyst on day 5: ≥ 80
Sterilization method	Aseptic filtration	Aseptic filtration
Storage conditions	Store dark at +2 to +8°C	Store dark at +2 to +8°C
Bottle	Nalgene PETG bottle with HDPE closure and tamper evident seal	Nalgene PETG bottle with HDPE closure and tamper evident seal
<p>The subject and predicate device have the same Indications for Use and have the same intended use.</p> <p>The subject and predicate device have different technological features, including different ingredients and specifications. The different technological characteristics, including composition and specifications, do not raise different questions of safety and effectiveness.</p>		

## 8. Summary of Non-Clinical Performance Testing

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

- Aseptic filling validation study per ISO 13408-1:2008 and ISO 13408-2:2018
- Sterility testing per USP <71> (acceptance criterion: no microbial growth)
- Bacterial endotoxins testing per USP <85> (acceptance criterion: <0.25 EU/ml)
- pH measurements per USP <791>
- Osmolality per USP <785>
- Mouse Embryo Assay (MEA) using established protocol:

One-cell mouse embryos were cultured in test medium droplets. The percentage of embryos developed to the expanded blastocyst stage within 96 hours were assessed in comparison with the control group. The acceptance specification is “1-cell: ≥ 80% embryos developed to expanded blastocyst at 96 hours.

- Shelf-life testing was conducted to ensure that the following product specifications are met at time zero and end of shelf-life: pH, osmolality, sterility, endotoxin, and 1-cell MEA.
- Open/close stability testing was conducted to ensure that the following product specifications are met at two weeks after opening of bottles: pH, osmolality sterility, endotoxin, and 1-cell MEA.
- Transportation testing was conducted according to ASTM D4169-16 to ensure that package integrity and device performance are maintained.
- Biocompatibility studies were performed on the patient-contacting devices as follows:



- Cytotoxicity testing according to ISO 10993-5:2009
- Tests for Irritation and Skin Sensitization according to ISO 10993-10:2010, Guinea Pig Maximization Sensitization Test
- Tests for Irritation and Skin Sensitization according to ISO 10993-10:2010, Vaginal Mucosal Irritation Study in Rabbits

The patient-contacting devices were shown to be non-cytotoxic, non-sensitizing, and non-irritating.

## **9. Conclusion**

The nonclinical performance testing described above demonstrate that Gx-IVF™, Gx-TL™, and Gx-MOPS™ PLUS are as safe and effective as the predicate devices and supports a determination of substantial equivalence.