March 21, 2025

CaseBioscience, Inc.
Monica Mezezi
CEO/President
24 Norwich Street East
Guelph, Ont N1H 2G6
CANADA

Re: K242107
Trade/Device Name: CaseMONO™ Culture (CMON);
CaseMONO™ w/HEPES (WHMO);
CaseBioscience® HTF (HTFC);
CaseBioscience® HTF w/HEPES (HHTF)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 18, 2024
Received: February 19, 2025

Dear Monica Mezezi:

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)*
K242107

Device Name
CaseMONO™ Culture (CMON); CaseMONO™ w/HEPES (WHMO); CaseBioscience® HTF (HTFC); CaseBioscience® HTF w/ HEPES (HHTF)

Indications for Use *(Describe)*

CaseMONO™ Culture is intended for use for culture of embryos from fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus.

CaseBioscience® HTF is intended for use for the culture of embryos to the cleavage stage (Day 3). This device can be used for transfer of embryos to the uterus.

CaseMONO w/HEPES™ is intended for use in short-term handling and manipulating gametes and embryos, including washing and intracytoplasmic sperm injection (ICSI). This medium is not intended for transferring embryos to the uterine cavity.

CaseBioscience® HTF w/HEPES is intended for use in short-term handling and manipulating gametes embryos, including washing and intracytoplasmic sperm injection (ICSI). This medium is not intended for transferring embryos to the uterine cavity.

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
K242107

I. SUBMITTER

Applicant: CaseBioscience, Inc.

Address: 24 Norwich Street East, Guelph, Ont N1H 2G6 CAN
Phone: 1 (226) 243-6483
Contact Person: Monica Mezezi, CEO/President
Email: regulatory@casebioscience.com

Date Prepared: March 20, 2025

II. DEVICE

Trade Name: CaseMONO™ Culture (CMON); CaseMONO™ w/HEPES (WHMO); CaseBioscience® HTF (HTFC); CaseBioscience® HTF w/HEPES (HHTF)
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

Giftlife™ Fertilization Medium; Giftlife™ Cleavage Medium; Giftlife™ Blastocyst Medium Giftlife™ Single Step Medium (K240149) from Gimbo Medical Technology Shenzhen Co., Ltd.

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

IV. DEVICE DESCRIPTION

CaseMONO Culture, CaseMONO w/HEPES, CaseBioscience HTF, and CaseBioscience HTF w/HEPES are intended for use during in vitro procedures for gamete/embryo culture and one step media.

CaseMONO Culture is intended for use for culture of embryos from fertilization to the blastocyst stage. This device is a one-step media and can be used for transfer of embryos to the uterus.

CaseMONO w/HEPES is intended for use in short-term handling and manipulating gametes and embryos, including washing and intracytoplasmic sperm injection (ICSI).

CaseBioscience HTF is intended for use for the culture of embryos to the cleavage stage (Day 3). This device is not a one-step medium but can be used for transfer of embryos to the uterus.

CaseBioscience HTF w/HEPES is intended for use in short-term handling and manipulating gametes and embryos, including washing and intracytoplasmic sperm injection (ICSI).

CaseMONO Culture and CaseMONO w/HEPES have almost identical composition with differences in amount of NaHCO3 and Phenol red and presence of HEPES in CaseMONO w/HEPES. Similarly, CaseBioscience HTF and CaseBioscience HTF w/HEPES have an almost identical composition with the exception of HEPES present in CaseBioscience HTF w/HEPES and minor difference in composition for NaCl, Sodium L-lactate and Phenol red. CaseMONO Culture and CaseMONO w/HEPES contain EDTA. All media formulations contain antibiotic gentamicin.

The four solutions are aseptically filtered (storage vials sterilized by radiation) and provided in PETG square media bottles with HDPE screw-style caps. They have a shelf-life of 90 days when stored at 2-8°C. Media in the vials can be used for up to seven days after vial opening.

V. INDICATIONS FOR USE

CaseMONO™ Culture is intended for use for culture of embryos from fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus.

CaseBioscience® HTF is intended for use for the culture of embryos to the cleavage stage (Day 3). This device can be used for transfer of embryos to the uterus.

CaseMONO w/HEPES™ is intended for use in short-term handling and manipulating gametes and embryos, including washing and intracytoplasmic sperm injection (ICSI). This medium is not intended for transferring embryos to the uterine cavity.

CaseBioscience® HTF w/HEPES is intended for use in short-term handling and manipulating gametes embryos, including washing and intracytoplasmic sperm injection (ICSI). This medium is not intended for transferring embryos to the uterine cavity.

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	K242107 Subject Device	K240149 Predicate Device	Comparison
Indications for Use	CaseMONO™ Culture is intended for use for culture of embryos from fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus. CaseBioscience® HTF is intended for use for the culture of embryos to the cleavage stage (Day 3). This device can be used for transfer of embryos to the uterus. CaseMONO w/HEPES™ is intended for use in short-term handling and manipulating gametes and embryos, including washing and intracytoplasmic sperm injection (ICSI). This medium is not intended for transferring embryos to the uterine cavity. CaseBioscience® HTF w/HEPES is intended for use in short-term handling and manipulating gametes embryos, including washing and intracytoplasmic sperm injection (ICSI). This medium is not intended for transferring embryos to the uterine cavity.	Giftlife Fertilization Medium is intended for use during in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) procedures and culture to the two pronuclei (zygote) stage of development. Giftlife Cleavage Medium is intended for use during in vitro fertilization (IVF) for culture of embryos from pronucleate stage to day 2 or day 3. This medium is not intended for transferring embryos to the uterine cavity. Giftlife Blastocyst Medium is intended for use during in vitro fertilization (IVF) for culture of embryos from day 3 to the blastocyst stage. This medium is not intended for transferring embryos to the uterine cavity. Giftlife Single Step Medium is used for culture of embryos from fertilization to the blastocyst stage.	There are differences in the wording of the indications for use statements for the subject and predicate device; however overall, the indications for use statements for the predicate device are similar in intended use for embryo culture, handling, and use during fertilization procedures.

Comparison Item	K242107 Subject Device	K240149 Predicate Device	Comparison
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Composition	NaCl, KCl, MgSO4·7H2O, KH2PO4, CaCl2·2H2O, NaHCO3, Glucose, Sodium pyruvate, Sodium L-lactate, GlyGln Essential and Non-Essential Amino Acids, Gentamicin, Phenol Red, HEPES, EDTA, Water	Not available publicly	**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	7.2-7.4 (CaseMONO Culture & CaseBioscience HTF) 7.2-7.6 (CaseMONO w/HEPES & CaseBioscience HTF w/HEPES)	Not available publicly	**Different:** The differences in pH specifications do not raise different questions of S&E.
Osmolality (mOsm/kg)	260-270 mOsm/kg (CaseMONO Culture) 285-295 mOsm/kg (CaseBioscience HTF) 260-270 mOsm/kg (CaseMONO w/HEPES) 285-295 mOsm/kg (CaseBioscience HTF w/HEPES)	Not available publicly	**Different:** The differences in osmolality specifications do not raise different questions of S&E.

Comparison Item	K242107 Subject Device	K240149 Predicate Device	Comparison
Bacterial Endotoxin	< 0.1 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 120 hours for CaseMONO ▪ One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst after 96 hours exposure to CaseBioscience HTF ▪ One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to CaseMONO w/HEPES ▪ One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to CaseBioscience HTF w/HEPES	Not available publicly	**Different:** The differences in MEA specifications do not raise different questions of S&E.
Sterilization Method	Aseptic Filtration Vials are sterilized via radiation	Not available publicly	**Similar**
Shelf-Life	90 days	Not available publicly	**Different:** The differences in

Comparison Item	K242107 Subject Device	K240149 Predicate Device	Comparison
			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 13408-1:2008 & A1:2013 and ISO 13408-2:2018.
    - 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.
- Vial 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)].
- Shelf-life testing was conducted to support a 90-days shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after aging at 2-8℃:
    - Appearance: All of the solutions should be without precipitates

- pH per USP <791>: 7.2-7.4 (CaseMONO Culture & CaseBioscience HTF); 7.2-7.6 (CaseMONO w/HEPES & CaseBioscience HTF w/HEPES)
- Osmolality per USP <785>: 260-270 mOsm/kg (CaseMONO Culture); 285-295 mOsm/kg (CaseBioscience HTF); 260-270 mOsm/kg (CaseMONO w/HEPES); 285-295 mOsm/kg (CaseBioscience HTF w/HEPES)
- Sterility per USP <71>: No microbial growth
- Bacterial endotoxin per USP <85>: < 0.1 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 120 hours for CaseMONO
    - One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst after 96 hours exposure to CaseBioscience HTF
    - One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to CaseMONO w/HEPES
    - One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to CaseBioscience HTF w/HEPES

- Transportation testing per ASTM D4169-22 and cap/seal leak testing using a method equivalent to USP <1207.2> on transportation-conditioned devices.
- Biocompatibility testing was conducted on the patient contacting subject media (CaseMONO Culture and CaseBioscience HTF) intended for transfer of embryos to uterine cavity 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 CaseMONO™ Culture (CMON); CaseMONO™ w/HEPES (WHMO); CaseBioscience® HTF (HTFC); CaseBioscience® HTF w/HEPES (HHTF) is as safe and effective as the predicate device and supports a determination of substantial equivalence.