



February 20, 2026

CaseBioscience Inc.
Monica Mezezi
CEO/President
24 Norwich Street East
Guelph, Ont N1H2G6
CANADA

Re: K252672
Trade/Device Name: CaseBio™ Culture w/HSA (CMH5); CaseBio™
Handling w/HSA (WHH5)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media And Supplements
Regulatory Class: II
Product Code: MQL
Received: February 4, 2026

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

510(k) Number (if known)
K252672

Device Name
CaseBio™ Culture w/HSA (CMH5); CaseBio™ Handling w/HSA (WHH5)

Indications for Use (Describe)

CaseBio™ Culture w/HSA 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.

CaseBio™ Handling w/HSA 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.

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.

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510(k) Summary
K252672

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: February 19, 2026

II. DEVICE

Trade Name: CaseBio™ Culture w/HSA (CMH5); CaseBio™ Handling w/HSA (WHH5)
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

CaseMONO™ Culture (CMON); CaseMONO™ w/HEPES (WHMO); (K242107) from CaseBioscience, Inc.

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

IV. DEVICE DESCRIPTION

CaseBio™ Culture w/HSA (CMH5) and CaseBio™ Handling w/HSA (WHH5) are intended for use during in vitro procedures for gamete/embryo culture and one step media.

CaseBio™ Culture w/HSA 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.

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

CaseBio™ Culture w/HSA (CMH5) and CaseBio™ Handling w/HSA (WHH5) have almost identical composition with differences in amount of NaHCO₃ and Phenol red and presence of HEPES in CaseBio™ Handling w/HAS. Both formulations contain gentamicin and human serum albumin.

The two 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

CaseBio™ Culture w/HSA 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.

CaseBio™ Handling w/HSA 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.

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	K252672 Subject Device	K242107 Predicate Device	Comparison
Indication for Use	CaseBio™ Culture w/HSA is intended for use for culture of embryos from	CaseMONO™ Culture is intended for use for culture of embryos from	The indications for use statement

Comparison Item	K252672 Subject Device	K242107 Predicate Device	Comparison
	<p>fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus.</p> <p>CaseBio™ Handling w/HSA 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.</p>	<p>fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus.</p> <p>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.</p>	<p>for CaseBio™ Culture w/HSA is identical to the predicate device (Case MONO Culture). It is a one-step media intended to for use for culturing embryos and for transfer to uterus. The indications for use statement for CaseBio™ Handling w/HSA is identical to the predicate device (CaseMONO w/HEPES) and is intended for handling gametes and embryos and is additionally indicated for manipulating of embryos</p>
Conditions for Use	Prescription Use Only	Prescription Use Only	Same
Composition	NaCl, KCl, MgSO ₄ ·7H ₂ O, KH ₂ PO ₄ , CaCl ₂ ·2H ₂ O, NaHCO ₃ , Glucose, Sodium pyruvate, Sodium L-lactate,	NaCl, KCl, MgSO ₄ ·7H ₂ O, KH ₂ PO ₄ , CaCl ₂ ·2H ₂ O, NaHCO ₃ , Glucose, Sodium pyruvate, Sodium	Different: The subject device and predicate

Comparison Item	K252672 Subject Device	K242107 Predicate Device	Comparison
	GlyGln Essential and Non-Essential Amino Acids, Gentamicin, Phenol Red, HEPES, EDTA, HSA, HEPES, Water	L-lactate, GlyGln Essential and Non-Essential Amino Acids, Gentamicin, Phenol Red, HEPES, EDTA, HEPES, Water	devices have differences in media formulation. These differences in composition do not raise different questions of S&E.
pH	7.2-7.4	7.2-7.6	Different: The differences in pH specifications do not raise different questions of S&E.
Osmolality (mOsm/kg)	260-270 mOsm/kg	260-270 mOsm/kg	Same
Bacterial Endotoxin	< 0.1 EU/mL	< 0.1 EU/mL	Same
Mouse Embryo Assay	One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 120 hours for CaseBio™ Culture w/HSA. One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to CaseBio™ Handling w/HSA.	One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 120 hours for CaseMONO One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to CaseMONO w/HEPES	Different: The differences in MEA specifications do not raise different questions of S&E.
Sterilization Method	Aseptic Filtration Vials are sterilized via	Aseptic Filtration Vials are sterilized via	Same

Comparison Item	K252672 Subject Device	K242107 Predicate Device	Comparison
	radiation	radiation	
Shelf-Life	90 days	90 days	Same

As shown in the table above, there are differences in technological characteristics of the subject and predicate devices, but they have the same intended use. However, as stated in the table, 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 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°C:
 - Appearance: All of the solutions should be without precipitates
 - pH per USP <791>: 7.2-7.4
 - Osmolality per USP <785>: 260-270 mOsm/kg

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- 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: $\geq 80\%$ embryos developed to expanded blastocyst at 120 hours for CaseBio™ Culture w/HSA.
 - One-Cell MEA: $\geq 80\%$ embryos developed to expanded blastocyst at 96 hours after a 1-hour exposure to CaseBio™ Handling w/HSA.
 - Transportation testing per ASTM D4169-22 and cap/seal leak testing using a method equivalent to USP <1207.2> on transportation-conditioned devices.

VIII. CONCLUSION

The results of the performance testing described above demonstrate that CaseBio™ Culture w/HSA (CMH5) and CaseBio™ Handling w/HSA (WHH5) are as safe and effective as the predicate device and supports a determination of substantial equivalence.