

**K242107 CaseMONO™ Culture (CMON)**Mar 21, 2025  
246 days to decisionK242107 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k242107/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jul 18, 2024
Decision date	Mar 21, 2025
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CaseMONO™ w/HEPES (WHMO); CaseBioscience® HTF (HTFC); CaseBioscience® HTF w/HEPES (HHTF)

**APPLICANT**

---

Company	<b>Casebioscience, Inc.</b>
Location	Guelph, CA
Contact	Monica Mezezi
510(k) history	2 submissions · 2 cleared · 2025-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242107/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026