

**K252672 CaseBio™ Culture w/HSA (CMH5)**Feb 20, 2026  
179 days to decisionK252672 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k252672/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Aug 25, 2025
Decision date	Feb 20, 2026
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CaseBio™ Handling w/HSA (WHH5)

**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/k252672/> 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 13, 2026