

K231370 Dewin Blastocyst Medium (with HSA and without HSA)Aug 4, 2023
84 days to decisionK231370 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k231370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	May 12, 2023
Decision date	Aug 4, 2023
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Donnevie Medical Technology (Shanghai) Co. , Ltd.
Location	Shanghai, CN
Contact	Hannah Hang Yin
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231370/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026