

K212426 Dewin Reproductive Media (Dewin Fertilization Medium [with HSA and without HSA] and Dewin Cleavage Medium [with HSA and without HSA])Jun 16, 2022
316 days to decisionK212426 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k212426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Aug 4, 2021
Decision date	Jun 16, 2022
Days to decision	316 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Stuart R. Goldman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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