

K251637 Dewin Reproductive Media (Dewin Gamete Buffer [with HSA and without HSA])Aug 27, 2025
90 days to decisionK251637 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k251637/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Reproductive (MQL) |
| Date received | May 29, 2025 |
| Decision date | Aug 27, 2025 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Dewin Follicle Flushing Solution, Dewin One Step medium [with HSA and without HSA]) |

APPLICANT

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

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