

K251932 Spectra PlatinumNov 25, 2025
154 days to decisionK251932 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k251932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 24, 2025
Decision date	Nov 25, 2025
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Uzinmedicare Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	Soyeon Lim
510(k) history	4 submissions · 4 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251932/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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