

K220926 Spectra WearableDec 12, 2022
256 days to decisionK220926 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k220926/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Mar 31, 2022
Decision date	Dec 12, 2022
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Gms Consulting
Contact	Im DoGyun

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220926/> 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 25, 2026