

**K250208 SPECTRA Wearable 2**Apr 6, 2026  
437 days to decisionK250208 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250208/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jan 24, 2025
Decision date	Apr 6, 2026
Days to decision	437 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uzinmedicare Co., Ltd.</b>
Location	Gyeonggi-Do, KR
Contact	Dain Jang
510(k) history	4 submissions · 4 cleared · 2022-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>GMSC Co., Ltd.</b>
Contact	Jong-Hyun Kim

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250208/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026