

**K251423 Spectra S1 Pro**Feb 6, 2026  
274 days to decisionK251423 · Product code: **HGX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k251423/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	May 8, 2025
Decision date	Feb 6, 2026
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Spectra S2 Pro

**APPLICANT**

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Company	<b>Uzinmedicare Co., Ltd.</b>
Location	Gyeonggi-Do, KR
Contact	Soyeon Lim
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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251423/> 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