FDA 510(k) Premarket Notification

K251423 Spectra S1 Pro

CLEARED

Feb 6, 2026
274 days to decision

K251423 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k251423/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**GMSC Co., Ltd.**
Contact	Jong-Hyun Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov