FDA 510(k) Premarket Notification

K250208 SPECTRA Wearable 2

CLEARED

Apr 6, 2026
437 days to decision

K250208 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k250208/

SUBMISSION DETAILS

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

Company	**Uzinmedicare Co., Ltd.**
Location	Gyeonggi-Do, KR
Contact	Dain Jang
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