

**K162415 Spectra 9Plus**Mar 15, 2017  
198 days to decisionK162415 · Product code: **HGX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k162415/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Aug 29, 2016
Decision date	Mar 15, 2017
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uzinmedicare Company</b>
Location	Seoul, KR
Contact	Nathan Ahn
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162415/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026