

**K251977 electric breast pump (FZ-P8)**Oct 22, 2025  
117 days to decisionK251977 · Product code: **HGX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k251977/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 27, 2025
Decision date	Oct 22, 2025
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	electric breast pump (YH-P8); electric breast pump (YH-P8X)

**APPLICANT**

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Company	<b>Ningbo Youhe Electrical Appliance Technology Co., Ltd.</b>
Location	Cixi, CN
Contact	Haifeng Hua
510(k) history	4 submissions · 4 cleared · 2017-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Huaxiajamei (Beijing) Information Consulting Co.,Ltd</b>
Contact	Linda Li

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251977/> 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 14, 2026