

K254125 Electric Breast Pump (HL-3058 II Pro)May 13, 2026
145 days to decisionK254125 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k254125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Dec 19, 2025
Decision date	May 13, 2026
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fimilla (Shanghai) Maternity & Baby Articles Co., Ltd.
Location	Shanghai, CN
Contact	Shulin Wu
510(k) history	4 submissions · 4 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	Feiyang Drug & Medical Consulting Technical Service Group
Contact	Youshan Gong

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.netDevice record: <https://www.510kdatabase.net/k254125/> Data sourced from FDA 510(k) public records (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. - Generated June 8, 2026