

**K250843 Wearable Breast Pump (Model FS12A)**Jul 31, 2025  
133 days to decisionK250843 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250843/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Breast, Powered (HGX)
Date received	Mar 20, 2025
Decision date	Jul 31, 2025
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Wearable Breast Pump (Model FS12B)

**APPLICANT**

---

Company	<b>Shenzhen TPH Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Xiaoyan Yang
510(k) history	19 submissions · 19 cleared · 2022-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250843/> 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 13, 2026