

K250383 Wearable Breast Pump (Model W6)Aug 20, 2025
190 days to decisionK250383 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Feb 11, 2025
Decision date	Aug 20, 2025
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250383/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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