

K241004 Wearable Breast Pump (ABP-1508PRO, ABP-1506, ABP-1306, ABP-1306 PRO, M1, M3, M8, M5, M6, K1, K2, K3, K5, ABP-1306PLUS, ABP-1308, M2)Sep 11, 2024
152 days to decisionK241004 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k241004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Apr 12, 2024
Decision date	Sep 11, 2024
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huizhou Lvb Maternal and Infant Supplies Co., Ltd.
Location	Huizhou, CN
Contact	Dongan Zhang
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Feiyong 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)

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