

K260346 Electric Breast Pump (BH627, BH628, BH707, BH709, BH813, BH816, BH110, H701, H1129, H1128, H620, H705, H706)Jun 12, 2026
129 days to decisionK260346 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k260346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Feb 3, 2026
Decision date	Jun 12, 2026
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Polybell (Guangzhou) Limited
Location	Guangzhou, CN
Contact	Qingliang Xu
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260346/> 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 July 11, 2026