

K253283 Momcozy Wearable Breast Pump (Model: BP334-, BP380-, BP420-, BP431-, BP400-, BP432-, BP434-)

Oct 29, 2025
30 days to decision

K253283 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k253283/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Breast, Powered (HGX)
Date received	Sep 29, 2025
Decision date	Oct 29, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Root Innovation Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Wendy Wen
510(k) history	9 submissions · 9 cleared · 2024-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k253283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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