

K233880 Momcozy Wearable Breast Pump (BP137)Mar 6, 2024
89 days to decisionK233880 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k233880/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Dec 8, 2023
Decision date	Mar 6, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Momcozy Wearable Breast Pump (BP141)

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Contact	Reanny Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233880/> 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 May 13, 2026