

K241680 Momcozy Wearable Breast Pump (BP311)Dec 20, 2024
192 days to decisionK241680 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k241680/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 11, 2024
Decision date	Dec 20, 2024
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle 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/k241680/> 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 14, 2026