

**K243629 Momcozy Wearable Breast Pump (BP311)**Dec 20, 2024  
25 days to decisionK243629 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243629/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Breast, Powered (HGX)
Date received	Nov 25, 2024
Decision date	Dec 20, 2024
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Momcozy Wearable Breast Pump (BP223); Momcozy Wearable Breast Pump (BP324); Momcozy Wearable Breast Pump (BP334); Momcozy Wearable Breast Pump (BP430)

**APPLICANT**

---

Company	<b>Shenzhen Root Innovation Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Amy Dong
510(k) history	9 submissions · 9 cleared · 2024-2026

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Shenzhen Root Innovation Technology Co., , Ltd.</b>
Contact	Amy Dong

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243629/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026