

K253946 Momcozy Wearable Breast Pump (S9 Pro, S9 Pro-A, S9 Pro-B, S9 Pro-C, S9 Pro-D, S9 ProY-A, S9 ProY-B, S9 ProY-C, S12 Pro, S12 Pro-A, S12 Pro-B, S12 Pro-C, S12 Pro-D, S12 ProY-A, S12 ProY-B, S12 ProY-C)

Apr 7, 2026
118 days to decision

K253946 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k253946/>

SUBMISSION DETAILS

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Breast, Powered (HGX) |
| Date received | Dec 10, 2025 |
| Decision date | Apr 7, 2026 |
| Days to decision | 118 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 | Caitlin Liang |
| 510(k) history | 9 submissions · 9 cleared · 2024-2026 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k253946/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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