

K250207 eufy Wearable Breast Pump S1 (T8D02)Aug 11, 2025
199 days to decisionK250207 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jan 24, 2025
Decision date	Aug 11, 2025
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	eufy Wearable Breast Pump E10 (T8D03)

APPLICANT

Company	Anker Innovations Limited
Location	Hongkong, CN
Contact	Darren Li
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Tracy Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250207/> 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