

**K220309 Wearable Breast Pump (Model S10)**Jun 27, 2022  
145 days to decisionK220309 · Product code: **HGX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k220309/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Feb 2, 2022
Decision date	Jun 27, 2022
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Lutejiacheng Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Johnny Dai
510(k) history	3 submissions · 3 cleared · 2022-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Eva Li

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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