

K221598 Wearable breast pumpDec 9, 2022
190 days to decisionK221598 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k221598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 2, 2022
Decision date	Dec 9, 2022
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mayborn (Uk) Limited
Location	Newcastle Upon Tyne,, GB
Contact	Sean Neasham
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Amber Pang

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

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