

K231595 Electric Breast PumpOct 26, 2023
147 days to decisionK231595 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k231595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 1, 2023
Decision date	Oct 26, 2023
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Changkun Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Wang Qingpeng
510(k) history	5 submissions · 5 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Contact	Reanny Wang

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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