

K211024 Electric Breast PumpFeb 11, 2022
311 days to decisionK211024 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k211024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Apr 6, 2021
Decision date	Feb 11, 2022
Days to decision	311 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shantou Huihengqi Electronic Technology Co., Ltd.
Location	Shantou, CN
Contact	Gensong Yang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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/k211024/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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