

K212564 Electric Breast PumpMay 6, 2022
266 days to decisionK212564 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k212564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Aug 13, 2021
Decision date	May 6, 2022
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Horigen Mother & Baby Products Co., Ltd.
Location	Shantou, CN
Contact	Changxin Chen
510(k) history	6 submissions · 6 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
Contact	Olivia Meng

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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