

K210936 Elvie StrideAug 25, 2021
149 days to decisionK210936 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k210936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Mar 29, 2021
Decision date	Aug 25, 2021
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chiaro Technology Limited
Location	London, GB
Contact	Carre King
510(k) history	2 submissions · 2 cleared · 2018-2021

REGULATORY CONSULTANT

Consulting firm	Contract In-House Counsel and Consultants, LLC
Contact	Marc C. Sanchez

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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