

K181863 Elvie PumpOct 10, 2018
90 days to decisionK181863 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jul 12, 2018
Decision date	Oct 10, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chiaro Technology Limited
Location	London, GB
Contact	Jonathan O'&Toole
510(k) history	2 submissions · 2 cleared · 2018-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181863/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026