

K190810 OPERA, OPERA ecoAug 30, 2019
154 days to decisionK190810 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Mar 29, 2019
Decision date	Aug 30, 2019
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unimom.Co
Location	Osan-Si, KR
Contact	Sang-Hyun Hong
510(k) history	4 submissions · 4 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190810/> 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 27, 2026