

K232608 Duo Hands-free Breast PumpApr 12, 2024
228 days to decisionK232608 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k232608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Breast, Powered (HGX)
Date received	Aug 28, 2023
Decision date	Apr 12, 2024
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medela, LLC
Location	Mchenry, IL, US
Contact	Jenni Vescovo
510(k) history	7 submissions · 7 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	Medela AG
Contact	Jenni Vescovo

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/k232608/> 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 14, 2026