FDA 510(k) Premarket Notification

K232608 Duo Hands-free Breast Pump

CLEARED

Apr 12, 2024
228 days to decision

K232608 · Product code: **HGX** · Obstetrics & Gynecology
Source: 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