FDA 510(k) Premarket Notification

K210759 Solo, Swing Maxi

CLEARED

Aug 11, 2021
149 days to decision

K210759 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k210759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Mar 15, 2021
Decision date	Aug 11, 2021
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medela, LLC**
Location	Mchenry, IL, US
Contact	Mike McAndrew
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