

K210759 Solo, Swing MaxiAug 11, 2021
149 days to decisionK210759 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210759/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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