

K251377 Magic InBraSep 18, 2025
139 days to decisionK251377 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k251377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	May 2, 2025
Decision date	Sep 18, 2025
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medela AG
Location	Ch-6340 Baar, CH
Contact	Tiana Steinhoff
510(k) history	30 submissions · 30 cleared · 2002-2025

REGULATORY CONSULTANT

Consulting firm	Medela, LLC
Contact	Tiana Steinhoff

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/k251377/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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