FDA 510(k) Premarket Notification

K251377 Magic InBra

CLEARED

Sep 18, 2025
139 days to decision

K251377 · Product code: **HGX** · Obstetrics & Gynecology
Source: 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