

**K253510 Freestyle Mini Hands-free**Apr 10, 2026  
156 days to decisionK253510 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k253510/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Nov 5, 2025
Decision date	Apr 10, 2026
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medela, LLC</b>
Location	Mchenry, IL, US
Contact	Jenni Vescovo
510(k) history	7 submissions · 7 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253510/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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