FDA 510(k) Premarket Notification

CLEARED

K150499 Freestyle Deluxe, Freestyle Solution Set, Freestyle Basic, Freestyle Motor Warranty

Apr 21, 2015
54 days to decision

K150499 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k150499/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Feb 26, 2015
Decision date	Apr 21, 2015
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k150499/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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