

K191653 Freestyle FlexOct 17, 2019
119 days to decisionK191653 · Product code: **HGX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Jun 20, 2019
Decision date	Oct 17, 2019
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026