

**K172067 One Mum Pumpset**Nov 29, 2017  
145 days to decisionK172067 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k172067/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Breast, Powered (HGX)
Date received	Jul 7, 2017
Decision date	Nov 29, 2017
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ardo Medical AG</b>
Location	Untergeri, CH
Contact	Roger Dubach
510(k) history	6 submissions · 6 cleared · 2001-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172067/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026