FDA 510(k) Premarket Notification

K212773 ARDO Alyssa

CLEARED

Apr 15, 2022
227 days to decision

K212773 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k212773/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Aug 31, 2021
Decision date	Apr 15, 2022
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ardo Medical AG**
Location	Unterageri, CH
Contact	Thomas Schlieper
510(k) history	6 submissions · 6 cleared · 2001-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Kristin Zielinski Duggan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov