FDA 510(k) Premarket Notification

K230672 Annabella Breast Pump

CLEARED

Aug 4, 2023
147 days to decision

K230672 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k230672/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Mar 10, 2023
Decision date	Aug 4, 2023
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Annabella , Ltd.**
Location	Kfar Saba, IL
Contact	Uri Yaffe
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Dalia Dickman Consulting**
Contact	Dalia Dickman

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