FDA 510(k) Premarket Notification

K230469 Compact Wearable Pump

CLEARED

Jun 30, 2023
129 days to decision

K230469 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k230469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Feb 21, 2023
Decision date	Jun 30, 2023
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lansinoh Laboratories**
Location	Alexandria, VA, US
Contact	Lindsay Ewers
510(k) history	2 submissions · 2 cleared · 2022-2023