FDA 510(k) Premarket Notification

K213311 Lucy Breast Pump

CLEARED

Feb 9, 2022
128 days to decision

K213311 · Product code: **HGX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k213311/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Oct 4, 2021
Decision date	Feb 9, 2022
Days to decision	128 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Willow Innovations, Inc.**
Location	Mountain View, CA, US
Contact	Nelson Lam
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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