FDA 510(k) Premarket Notification

K222597 BabySat 3

CLEARED

Jun 16, 2023
291 days to decision

K222597 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k222597/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 29, 2022
Decision date	Jun 16, 2023
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Owlet Babycare, Inc.**
Location	Lehi, UT, US
Contact	Tammy Lavery
510(k) history	2 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

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