FDA 510(k) Premarket Notification

K191574 OxSAT 100

CLEARED

Apr 9, 2020
300 days to decision

K191574 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k191574/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 14, 2019
Decision date	Apr 9, 2020
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**S.L.P. , Ltd.**
Location	Tel-Aviv, IL
Contact	Avi Yosef
510(k) history	5 submissions · 5 cleared · 2004-2020

REGULATORY CONSULTANT

Consulting firm	**S.L.P. Ltd. C/O Promedic, LLC**
Contact	Paul Dryden

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