FDA 510(k) Premarket Notification

K192340 OptoMonitor

CLEARED

Dec 12, 2019
106 days to decision

K192340 · Product code: **DXO** · Cardiovascular
Source: https://www.510kdatabase.net/k192340/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Aug 28, 2019
Decision date	Dec 12, 2019
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Opsens, Inc.**
Location	Quebec, CA
Contact	Marc Chaunet
510(k) history	10 submissions · 10 cleared · 2015-2026