FDA 510(k) Premarket Notification

K101995 CAPNOSTREAM 20P WITH MASIMO SPO2 BOARD

CLEARED

Jan 11, 2011
181 days to decision

K101995 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k101995/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jul 14, 2010
Decision date	Jan 11, 2011
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oridion Capnography, Inc.**
Location	Jerusalem, IL
Contact	RACHEL WEISSBROD
510(k) history	5 submissions · 5 cleared · 2006-2011