FDA 510(k) Premarket Notification

K153021 Fingertip Pulse Oximeter A310

CLEARED

Nov 22, 2016
404 days to decision

K153021 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k153021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Oct 15, 2015
Decision date	Nov 22, 2016
Days to decision	404 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Amemo, Inc.**
Location	Milpitas, CA, US
Contact	HUA XIE
510(k) history	1 submissions · 1 cleared · 2016-2016