FDA 510(k) Premarket Notification

K173045 Oximeter

CLEARED

Jun 5, 2018
250 days to decision

K173045 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k173045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 28, 2017
Decision date	Jun 5, 2018
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Greatmade Tech Limited**
Location	Shenzhen, CN
Contact	Mei Mei
510(k) history	1 submissions · 1 cleared · 2018-2018