FDA 510(k) Premarket Notification

K172792 Handheld Pulse Oximeter, Model SP-20

CLEARED

Nov 13, 2018
424 days to decision

K172792 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k172792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 15, 2017
Decision date	Nov 13, 2018
Days to decision	424 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Creative Industry Co., Ltd.**
Location	Flintville, TN, US
Contact	Jia Wang
510(k) history	11 submissions · 11 cleared · 2007-2021