FDA 510(k) Premarket Notification

K203854 Pulse Oximeter

CLEARED

Apr 23, 2021
113 days to decision

K203854 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k203854/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 31, 2020
Decision date	Apr 23, 2021
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Hexin Zondan Medical Equipment Co., Ltd.**
Location	Shenzhen, CN
Contact	John Liu
510(k) history	1 submissions · 1 cleared · 2021-2021