FDA 510(k) Premarket Notification

K212300 Pulse Oximeter

CLEARED

Feb 25, 2022
218 days to decision

K212300 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k212300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jul 22, 2021
Decision date	Feb 25, 2022
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Mericonn Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Jiang Chuanyuan
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Kevin Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov