FDA 510(k) Premarket Notification

K211400 Pulse Oximeter

CLEARED

Feb 11, 2022
282 days to decision

K211400 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k211400/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 5, 2021
Decision date	Feb 11, 2022
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Choice Electronic Technology Co., Ltd.**
Location	Beijing, CN
Contact	Haiying Zhao
510(k) history	14 submissions · 14 cleared · 2016-2024