FDA 510(k) Premarket Notification

K234110 Belun Ring BLR-200 (BLR-200)

CLEARED

Oct 11, 2024
289 days to decision

K234110 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k234110/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 27, 2023
Decision date	Oct 11, 2024
Days to decision	289 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Belun Technology Company Limited**
Location	Sha Tin, HK
Contact	Lap Wai Lydia Leung
510(k) history	5 submissions · 5 cleared · 2018-2024