FDA 510(k) Premarket Notification

K213430 Fingertip Pulse Oximeter

CLEARED

Dec 30, 2022
435 days to decision

K213430 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k213430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Oct 21, 2021
Decision date	Dec 30, 2022
Days to decision	435 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Witleaf Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Wu Tao
510(k) history	2 submissions · 2 cleared · 2022-2023

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