FDA 510(k) Premarket Notification

K240808 Pulse Oximeter (WS20A)

CLEARED

Oct 3, 2024
192 days to decision

K240808 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k240808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Mar 25, 2024
Decision date	Oct 3, 2024
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hunan Accurate Bio-Medical Technology Co., Ltd.**
Location	Changsha, Hunan, CN
Contact	Li Zhang
510(k) history	5 submissions · 5 cleared · 2014-2026

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Jie Yang

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