FDA 510(k) Premarket Notification

K243049 Pulse Oximeter (FS20P)

CLEARED

Jan 2, 2025
97 days to decision

K243049 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k243049/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 27, 2024
Decision date	Jan 2, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pulse Oximeter (FS20C); Pulse Oximeter (FS10C)

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