FDA 510(k) Premarket Notification

K210274 Fingertip Pulse Oximeter

CLEARED

Jul 30, 2021
179 days to decision

K210274 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k210274/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Feb 1, 2021
Decision date	Jul 30, 2021
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhuhai Linte Medical Instrument Co., Ltd.**
Location	Zhuhai, CN
Contact	Kezheng Ma
510(k) history	2 submissions · 2 cleared · 2021-2022

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

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Device record: https://www.510kdatabase.net/k210274/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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