

K213431 Handheld Pulse OximeterFeb 26, 2023
493 days to decisionK213431 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k213431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Oct 21, 2021
Decision date	Feb 26, 2023
Days to decision	493 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

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