FDA 510(k) Premarket Notification

K201887 VS Newborn Heart Rate Monitor

CLEARED

Jul 23, 2021
380 days to decision

K201887 · Product code: **DQA** · Cardiovascular
Source: https://www.510kdatabase.net/k201887/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jul 8, 2020
Decision date	Jul 23, 2021
Days to decision	380 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Surepulse Medical Limited**
Location	Nottingham, GB
Contact	James Carpenter
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies, LLC**
Contact	Allison Komiyama

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k201887/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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