FDA 510(k) Premarket Notification

K181270 Disposable SpO2 Sensors, Reusable SpO2 Sensors

CLEARED

Sep 7, 2018
116 days to decision

K181270 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k181270/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 14, 2018
Decision date	Sep 7, 2018
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orantech, Inc.**
Location	Shenzhen, CN
Contact	Yunxi Xiong
510(k) history	5 submissions · 5 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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