FDA 510(k) Premarket Notification

K171828 ETCO2 Sensor

CLEARED

May 31, 2018
345 days to decision

K171828 · Product code: **CCK** · Anesthesiology
Source: https://www.510kdatabase.net/k171828/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Jun 20, 2017
Decision date	May 31, 2018
Days to decision	345 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	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Mei Mei

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