FDA 510(k) Premarket Notification

K191602 APA Oxy Blade

CLEARED

Aug 2, 2019
46 days to decision

K191602 · Product code: **CCW** · Anesthesiology
Source: https://www.510kdatabase.net/k191602/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laryngoscope, Rigid (CCW)
Date received	Jun 17, 2019
Decision date	Aug 2, 2019
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Venner Medical (Singapore) Pte, Ltd.**
Location	Dallas, TX, US
Contact	Adrian P. Waterton
510(k) history	6 submissions · 6 cleared · 2010-2020

REGULATORY CONSULTANT

Consulting firm	**Brauer Device Consultants, LLC**
Contact	Christine Brauer

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