

K192285 CPR Face ShieldNov 25, 2020
461 days to decisionK192285 · Product code: **CBP** · Anesthesiology
Source: <https://www.510kdatabase.net/k192285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	Aug 22, 2019
Decision date	Nov 25, 2020
Days to decision	461 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Firstar Healthcare Company Limited (Guangzhou)
Location	Guangzhou, CN
Contact	Alice Zhao
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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