

K201871 Surgical MaskAug 12, 2020
36 days to decisionK201871 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 7, 2020
Decision date	Aug 12, 2020
Days to decision	36 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	C & S Paper Yunfu Co., Ltd.
Location	Luoding, CN
Contact	Xu Zhiming
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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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