

K210856 Purism Disposable Surgical MaskJul 28, 2021
127 days to decisionK210856 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 23, 2021
Decision date	Jul 28, 2021
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chuzhou Daddy&apos;S Choice Science and Technology Co., Ltd.
Location	Chuzhou, CN
Contact	Amie Yang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Nickita Alexiades

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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