

K203756 Disposable Surgical MaskJun 10, 2021
169 days to decisionK203756 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k203756/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 23, 2020
Decision date	Jun 10, 2021
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lucky Textile Industrial(Wuxi) Co., Ltd.
Location	Yixing, CN
Contact	Grace Tai
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203756/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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