

K202607 Surgical Mask - Level 3 - Blue - 50 pcs, Surgical Mask - Level 3 - White - 50 pcs, Procedure Mask - Level 3 - Blue - 50 pcs, Procedure Mask - Level 3 - White - 50 pcsApr 23, 2021
226 days to decisionK202607 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k202607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 9, 2020
Decision date	Apr 23, 2021
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	String King Lacrosse, LLC
Location	Gardena, CA, US
Contact	Thomas Frasca
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Robert V. Packard

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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