

K214094 ROKI Surgical MaskFeb 24, 2022
58 days to decisionK214094 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k214094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 28, 2021
Decision date	Feb 24, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roki Co., Ltd.
Location	Hamamatsu-Shi, JP
Contact	Takamasa Murata
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mic International
Contact	Fumiaki Kanai

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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