

K251902 Vitaform Procedural Mask - Blue (Vitaform Blue)Sep 17, 2025
89 days to decisionK251902 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k251902/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 20, 2025
Decision date	Sep 17, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary
Other names	Vitaform Procedural Mask with Shield (Vitaform-FS)

APPLICANT

Company	Vitacore Industries, Inc.
Location	Port Coquitlam, CA
Contact	Yuxuan Fan
510(k) history	1 submissions · 1 cleared · 2025-2025

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