

K212740 Puravita Medical Fold Flat Surgical MaskDec 2, 2021
94 days to decisionK212740 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212740/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 30, 2021
Decision date	Dec 2, 2021
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Puravita M, LLC
Location	Lindon, UT, US
Contact	Jefferson Nemelka
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Iuvo Consulting, LLC
Contact	Rhonda Alexander

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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