FDA 510(k) Premarket Notification

K222551 Humask Pro Vision, Humask Pro Vision 3000

CLEARED

Nov 10, 2022
79 days to decision

K222551 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k222551/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Aug 23, 2022
Decision date	Nov 10, 2022
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Entreprise Premont, Inc.**
Location	Louiseville, CA
Contact	Charlie Marchand
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Enterprise Premont, Inc.**
Contact	Charlie Marchand

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov