

K203064 ICU Health Surgical MaskMar 23, 2021
165 days to decisionK203064 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Oct 9, 2020
Decision date	Mar 23, 2021
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Plastikon Industries
Location	Hayward, CA, US
Contact	Paul Gutwald
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Hantel Technologies, Inc.
Contact	Mary Pascual Gallup

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203064/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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