

K203265 nPro Surgical MaskFeb 9, 2021
96 days to decisionK203265 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Nov 5, 2020
Decision date	Feb 9, 2021
Days to decision	96 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Np Medical, Inc.
Location	South Lyon, MI, US
Contact	Ruthann Rapp
510(k) history	4 submissions · 4 cleared · 1998-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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