

K200321 Novaerus NV1050Dec 28, 2020
322 days to decisionK200321 · Product code: **FRF** · General HospitalSource: <https://www.510kdatabase.net/k200321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cleaner, Air, Medical Recirculating (FRF)
Date received	Feb 10, 2020
Decision date	Dec 28, 2020
Days to decision	322 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Novaerus Us, Inc.
Location	Stamford, CT, US
Contact	Declan Kiely
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200321/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026