

K201220 Aerus Medical Guardian,model F170AJun 17, 2020
42 days to decisionK201220 · Product code: **FRA** · General Hospital
Source: <https://www.510kdatabase.net/k201220/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	May 6, 2020
Decision date	Jun 17, 2020
Days to decision	42 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Aerus Medical, LLC
Location	Dallas, TX, US
Contact	Andrew Eide
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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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