FDA 510(k) Premarket Notification

K201220 Aerus Medical Guardian,model F170A

CLEARED

Jun 17, 2020
42 days to decision

K201220 · 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