510(k) Premarket Notification

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Device Classification Name	Purifier, Air, Ultraviolet, Medical[22]
510(K) Number	K201220
Device Name	Aerus Medical Guardian,Model F170A
Applicant	Aerus Medical LLC 14841 Dallas Parkway, Suite 500, The Aberdeen Bldg. Dallas, TX 75254
Applicant Contact	Andrew Eide
Correspondent	THIRD PARTY REVIEW GROUP, LLC 25 Independence Blvd Warren, NJ 07059
Correspondent Contact	Dave Yungvirt
Regulation Number	880.6500[23]
Classification Product Code	FRA[24]
Date Received	05/06/2020
Decision Date	06/17/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Type	Traditional
Reviewed By Third Party	Yes
Combination Product	No

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Page Last Updated: 12/28/2020

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