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## 510(k) Premarket Notification



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**Device Classification Name** [Purifier, Air, Ultraviolet, Medical](#)<sup>22</sup>  
**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](#)<sup>23</sup>  
**Classification Product Code** [FRA](#)<sup>24</sup>  
**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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