

K220990 Qorda QD1Sep 14, 2022
163 days to decisionK220990 · Product code: **FRF** · General Hospital
Source: <https://www.510kdatabase.net/k220990/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cleaner, Air, Medical Recirculating (FRF)
Date received	Apr 4, 2022
Decision date	Sep 14, 2022
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Winix, Inc.
Location	Hwaseong-Si, KR
Contact	Daewoon Kang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	April Lee

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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