FDA 510(k) Premarket Notification

K220990 Qorda QD1

CLEARED

Sep 14, 2022
163 days to decision

K220990 · 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