

K251872 Biomoneta Avata RxNov 14, 2025
149 days to decisionK251872 · Product code: **FRF** · General Hospital
Source: <https://www.510kdatabase.net/k251872/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cleaner, Air, Medical Recirculating (FRF)
Date received	Jun 18, 2025
Decision date	Nov 14, 2025
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Biomoneta Research Private Limited
Location	Bengaluru, IN
Contact	Arindam Ghatak
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	I3cglobal Reghelps Pvt, Ltd.
Contact	Amrutha Rai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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