

K232926 Novalung ultimate kit (US)Apr 15, 2024
208 days to decisionK232926 · Product code: **QJZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k232926/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal System For Long-term Respiratory / Cardiopulmonary Failure (QJZ)
Date received	Sep 20, 2023
Decision date	Apr 15, 2024
Days to decision	208 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care Renal Therapies Group, LLC
Location	Waltham, MA, US
Contact	Amelia Huynh
Website	https://www.freseniusmedicalcare.com
510(k) history	50 submissions · 50 cleared · 2013-2026

Fresenius Medical Care Renal Therapies Group, LLC is a medical device manufacturer based in Waltham, US. The company specializes in renal therapy and dialysis technologies. The company has received FDA 510(k) clearances from total submissions since 2013. 96% of submissions focus on Gastroenterology & Urology devices, reflecting the company's core expertise in dialysis and renal replacement therapies. The latest clearance was in 2026, confirming active regulatory engagement. Recent cleared devices include hemodialysis systems, dialyzers, body composition monitors, and dial...

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Device record: <https://www.510kdatabase.net/k232926/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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