

**K191407 Novalung System**Feb 21, 2020  
269 days to decisionK191407 · Product code: **QJZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k191407/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal System For Long-term Respiratory / Cardiopulmonary Failure (QJZ)
Date received	May 28, 2019
Decision date	Feb 21, 2020
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius Medical Care Renal Therapies Group, LLC</b>
Location	Waltham, MA, US
Contact	Denise Oppermann
Website	<a href="https://www.freseniusmedicalcare.com">https://www.freseniusmedicalcare.com</a>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k191407/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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