

**K210661 SC+ Hemodialysis Machine, SC+ Dialysate Cartridge,  
SC+ Blood Tubeset**Aug 12, 2021  
161 days to decisionK210661 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k210661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 4, 2021
Decision date	Aug 12, 2021
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quanta Dialysis Technologies, Ltd.</b>
Location	Alcester, GB
Contact	Sam Drew
510(k) history	4 submissions · 4 cleared · 2020-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210661/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026