

**K222067 SC+ Hemodialysis Device, SC+ Dialysate Cartridge,
SC+ Blood Tube Set**Nov 10, 2022
120 days to decisionK222067 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k222067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 13, 2022
Decision date	Nov 10, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222067/>. Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026