

**K193670 SC+ Haemodialysis Machine, SC+ Dialysate Cartridge,
SC+ Blood Tube Set**Dec 23, 2020
358 days to decisionK193670 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k193670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 31, 2019
Decision date	Dec 23, 2020
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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