

K242269 SC+ Hemodialysis Device (SC-14269)Nov 1, 2024
92 days to decisionK242269 · Product code: **ONW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialysis System For Home Use (ONW)
Date received	Aug 1, 2024
Decision date	Nov 1, 2024
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Dialysate Cartridge (SC-14656); Blood Tube Set (SC-14651)

APPLICANT

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

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