CLEARED

K210661 SC+ Hemodialysis Machine, SC+ Dialysate Cartridge, SC+ Blood Tubeset

Aug 12, 2021
161 days to decision

K210661 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k210661/

SUBMISSION DETAILS

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

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