

K193005 DIMI RRT SystemAug 28, 2020
305 days to decisionK193005 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k193005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 28, 2019
Decision date	Aug 28, 2020
Days to decision	305 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Dialco Medical, Inc.
Location	Toronto, CA
Contact	Danijela Domljanovic
510(k) history	1 submissions · 1 cleared · 2020-2020

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