

K193542 Clearum HS Family, Clearum HS Models: HS 13, HS 15, HS 17, HS 20, HS 22Oct 8, 2020
293 days to decisionK193542 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k193542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 20, 2019
Decision date	Oct 8, 2020
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bellco Srl
Location	Mirandola, IT
Contact	Rekha Roveri
510(k) history	3 submissions · 3 cleared · 2016-2023

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