FDA 510(k) Premarket Notification

K231406 ClearumTM HS

CLEARED

Jun 14, 2023
30 days to decision

K231406 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k231406/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 15, 2023
Decision date	Jun 14, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Mozarc Medical**
Contact	Michele Gust

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov