FDA 510(k) Premarket Notification

CLEARED

K232171 Purema® H Hemoconcentrator (EtO Sterilized)

Feb 7, 2024
201 days to decision

K232171 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 21, 2023
Decision date	Feb 7, 2024
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tecnoideal America**
Location	Derwood, MD, US
Contact	Paul Rodbhajon
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Amarex Clinical Research, LLC**
Contact	Ahmad Bayat

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