FDA 510(k) Premarket Notification

K010805 PRISMA SYSTEM

CLEARED

Aug 6, 2002
508 days to decision

K010805 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k010805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 16, 2001
Decision date	Aug 6, 2002
Days to decision	508 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Gambro Renal Products**
Location	Lakewood, CO, US
Contact	SUZANNE DENNIS
510(k) history	24 submissions · 23 cleared · 2000-2012