FDA 510(k) Premarket Notification

K133807 MARS MONITOR ITC US, MARS TREATMENT KIT TYPE 1116/1 - X-MARS US, PRISMAFLEX CONTROL UNIT

CLEARED

Mar 26, 2014
100 days to decision

K133807 · Product code: **FLD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k133807/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Hemoperfusion, Sorbent (FLD)
Date received	Dec 16, 2013
Decision date	Mar 26, 2014
Days to decision	100 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Gambro Renal Products, Inc.**
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	13 submissions · 13 cleared · 2004-2014