

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133807/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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