FDA 510(k) Premarket Notification

K130100 COMINED STANDARD SOLUTION

CLEARED

Apr 18, 2013
93 days to decision

K130100 · Product code: **FKH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k130100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solution-test Standard-conductivity, Dialysis (FKH)
Date received	Jan 15, 2013
Decision date	Apr 18, 2013
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mesa Laboratories, Inc.**
Location	Lakewood, CO, US
Contact	JAMIE LOUIE
510(k) history	9 submissions · 9 cleared · 2004-2020