FDA 510(k) Premarket Notification

CLEARED

K131814 AMECATH DUAL LUMEN IMPLANTED HEMODIALYSIS CATHETER

Jul 26, 2013
36 days to decision

K131814 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k131814/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Jun 20, 2013
Decision date	Jul 26, 2013
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ameco Medical Industries**
Location	Mason, NH, US
Contact	Ray Kelly
510(k) history	6 submissions · 5 cleared · 2011-2016