FDA 510(k) Premarket Notification

K013160 POURCHEZ XPRESSO TWIN LIMEN CHRONIC HEMODIALYSIS CATHETER

CLEARED

Apr 11, 2002
202 days to decision

K013160 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k013160/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Sep 21, 2001
Decision date	Apr 11, 2002
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spire Biomedical, Inc.**
Location	Bedford, MA, US
Contact	DONALD FICKETT
510(k) history	16 submissions · 12 cleared · 2002-2008