FDA 510(k) Premarket Notification

K012948 MODIFICATION TO VAXCEL DIALYSIS CATHETER

CLEARED

Oct 3, 2001
29 days to decision

K012948 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k012948/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Sep 4, 2001
Decision date	Oct 3, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific/Medi-Tech**
Location	Natick,, MA, US
Contact	NICHOLAS CONDAKES
510(k) history	5 submissions · 5 cleared · 2001-2002