FDA 510(k) Premarket Notification

K042016 DATASCOPE PROGUIDE CHRONIC DIALYSIS CATHETER

CLEARED

Sep 23, 2004
58 days to decision

K042016 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k042016/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Jul 27, 2004
Decision date	Sep 23, 2004
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Datascope Corp.**
Location	Mchenry, IL, US
Contact	PATRICE NAPODA
510(k) history	136 submissions · 135 cleared · 1976-2019