FDA 510(k) Premarket Notification

K180070 SpeediCath Flex Coude Pro

CLEARED

Feb 2, 2018
24 days to decision

K180070 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k180070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Jan 9, 2018
Decision date	Feb 2, 2018
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast**
Location	Plymouth, MN, US
Contact	Troy Thome
Website	http://www.coloplast.com/
510(k) history	15 submissions · 14 cleared · 2018-2024