FDA 510(k) Premarket Notification

K190620 SpeediCath Flex Coude Pro

CLEARED

Jul 10, 2019
121 days to decision

K190620 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k190620/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Mar 11, 2019
Decision date	Jul 10, 2019
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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