FDA 510(k) Premarket Notification

CLEARED

K183461 Rusch Flocath Hydrophilic Intermittent Catheter, Rusch MMG Hydrophilic Intermittent Catheter

May 8, 2019
145 days to decision

K183461 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k183461/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Dec 14, 2018
Decision date	May 8, 2019
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Teleflexmedical, Inc.**
Location	Jeffrey, NH, US
Contact	Lori Pfohl
510(k) history	64 submissions · 61 cleared · 1985-2024