FDA 510(k) Premarket Notification

CLEARED

K190527 GlidePath Long-Term Hemodialysis Catheters, HemoStar Long-Term Hemodialysis Catheters, HemoStar XK Long-Term Hemodialysis Catheters

Mar 5, 2020
367 days to decision

K190527 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k190527/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Mar 4, 2019
Decision date	Mar 5, 2020
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**C. R. Bard**
Location	Salt Lake Ciy,, UT, US
Contact	Jonathan Holmes
Website	http://www.crbard.com/
510(k) history	9 submissions · 8 cleared · 2012-2020

REGULATORY CONSULTANT

Consulting firm	**Bard Access Systems, Inc.**
Contact	Joan Bergstrom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov