FDA 510(k) Premarket Notification

CLEARED

K202150 GlidePath 7.5F Long-Term Dialysis Catheter

Nov 18, 2020
107 days to decision

K202150 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k202150/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Aug 3, 2020
Decision date	Nov 18, 2020
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	Joan Bergstrom
Website	https://www.bd.com
510(k) history	644 submissions · 609 cleared · 1976-2026

C.R. Bard, Inc. is a developer, manufacturer, and marketer of medical technologies headquartered in Covington, US. The company specializes in vascular medicine, urology, oncology, and surgical specialty devices. C.R. Bard maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions spanning 1976 to 2026. The company's portfolio encompasses cardiovascular devices, gastroenterology and urology products, and general surgical technologies. Recent clearances include temporary pacing electrode catheters, thrombectomy systems, and ...