FDA 510(k) Premarket Notification

K170158 PowerGlide ST Midline Catheter

CLEARED

Jun 1, 2017
134 days to decision

K170158 · Product code: **PND** · General Hospital
Source: https://www.510kdatabase.net/k170158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Midline Catheter (PND)
Date received	Jan 18, 2017
Decision date	Jun 1, 2017
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	JACOB LEE
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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k170158/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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