

K153190 Zenysis Short-Term Dialysis CatheterJan 5, 2016
63 days to decisionK153190 · Product code: **MPB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Nov 3, 2015
Decision date	Jan 5, 2016
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	SILVIA DE LA BARRA
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 ...
