

K163458 Zenysis Short-Term Dialysis CatheterApr 4, 2017
116 days to decisionK163458 · Product code: **MPB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k163458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Dec 9, 2016
Decision date	Apr 4, 2017
Days to decision	116 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 ...
