

K033294 HEMOSPLIT XK, HEMOSPLIT XK CATHETER, 16FR X 42 CM, KITNov 26, 2003
43 days to decisionK033294 · Product code: **MSD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k033294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Oct 14, 2003
Decision date	Nov 26, 2003
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	16FR X 19 CM, KIT WITH MICROINTRODUCER

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	GLENN NORTON
Website	https://www.bd.com
510(k) history	645 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 ...