FDA 510(k) Premarket Notification

K801637 FLUORO-MARK RADIOPAQUE ANATOMICAL MKR.

CLEARED

Aug 27, 1980
41 days to decision

K801637 · Product code: **KPK** · Cardiovascular
Source: https://www.510kdatabase.net/k801637/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Ostia, Aorto-saphenous Vein (KPK)
Date received	Jul 17, 1980
Decision date	Aug 27, 1980
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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