FDA 510(k) Premarket Notification

CLEARED

K043246 BRACHYSOURCE BRACHYTHERAPY SEED IMPLANTS

Feb 2, 2005
71 days to decision

K043246 · Product code: **KXK** · Radiology
Source: https://www.510kdatabase.net/k043246/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Nov 23, 2004
Decision date	Feb 2, 2005
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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