FDA 510(k) Premarket Notification

K910154 USCI ILLUMEN-8 8F PTCA GUIDING CATHETER

CLEARED

Apr 9, 1991
85 days to decision

K910154 · Product code: **DOY** · Toxicology
Source: https://www.510kdatabase.net/k910154/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (3-h), Goat Antibody, 2nd Antibody Sep. (DOY)
Date received	Jan 14, 1991
Decision date	Apr 9, 1991
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	JANET D BENSON
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 ...