FDA 510(k) Premarket Notification

CLEARED

K012902 POLY PER-Q-CATH SINGLE LUMEN PICC CATHETER, MODEL 3143100

Sep 10, 2001
12 days to decision

K012902 · Product code: **LJS** · General Hospital
Source: https://www.510kdatabase.net/k012902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Aug 29, 2001
Decision date	Sep 10, 2001
Days to decision	12 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	POLY PER-Q-CATH DUAL LUMEN PICC CATHETER, MODEL 3246100

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	STEPHANIE A ERSKINE
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 ...