FDA 510(k) Premarket Notification

CLEARED

K073423 MRI POWERPORT IMPLANTED PORT WITH 9.6 FR SILICONE CATHETER

Dec 19, 2007
14 days to decision

K073423 · Product code: **LJT** · General Hospital
Source: https://www.510kdatabase.net/k073423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Dec 5, 2007
Decision date	Dec 19, 2007
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	SUSAN D SCOTT
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 ...