FDA 510(k) Premarket Notification

K171348 Pinpoint GT Needle Guide Kits

CLEARED

May 22, 2017
14 days to decision

K171348 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k171348/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	May 8, 2017
Decision date	May 22, 2017
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	Christopher M. Phillips
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 ...