

K171735 PowerLoc MAX Power-Injectable Infusion Set and SafeStep Huber Needle SetAug 8, 2017
57 days to decisionK171735 · Product code: PTI · General Hospital
Source: <https://www.510kdatabase.net/k171735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Non-coring (huber) Needle (PTI)
Date received	Jun 12, 2017
Decision date	Aug 8, 2017
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	Jeremy Tidwell
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 ...

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Device record: <https://www.510kdatabase.net/k171735/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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