FDA 510(k) Premarket Notification

CLEARED

K153440 PowerLoc MAX Power Injectable Infusion Set, SafeStep Huber Needle Set

Aug 18, 2016
265 days to decision

K153440 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k153440/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Nov 27, 2015
Decision date	Aug 18, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	Darlene Hull
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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k153440/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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