FDA 510(k) Premarket Notification

CLEARED

K241334 Semi-Floating Temporary Pacing Electrode Catheter, Bipolar, Stainless Steel Electrodes, 115 cm, 4Fr. (006221P)

Jan 31, 2025
266 days to decision

K241334 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k241334/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	May 10, 2024
Decision date	Jan 31, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Semi-Floating Temporary Pacing Electrode Catheter, Bipolar, Stainless Steel Electrodes, 115 cm, 5Fr. (006225P); Semi-Floating Temporary Pacing Electrode Catheter, Bipolar, Stainless Steel Electrodes, 125 cm, 6Fr. (006241P); Semi-Floating Temporary Pacing Electrode Catheter, Bipolar, Stainless Steel Electrodes, 125 cm, 7Fr. (006242P); NBIH™ Temporary Pacing Electrode Catheter,

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	Caitlin Bowles
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 ...