FDA 510(k) Premarket Notification

K132134 OPTIFIX ABSORBABLE FIXATION SYSTEM

CLEARED

Dec 2, 2013
144 days to decision

K132134 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k132134/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jul 11, 2013
Decision date	Dec 2, 2013
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	RADHIKA PONDICHERRY
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 ...