

K142808 CapSure Fixation System-Straight 5mm x 37 cm-30 Permanent fasteners, CapSure Fixation System-Straight 5mm x 37 cm-15 Permanent fasteners

Mar 9, 2015
161 days to decision

K142808 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k142808/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Sep 29, 2014
Decision date	Mar 9, 2015
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	Andrew Harrell
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 ...