

K160900 CapSure Fixation System - Straight 5mm x 37 cm – 30 Permanent fasteners, CapSure Fixation System - Straight 5mm x 37 cm – 15 Permanent fasteners

May 31, 2016
60 days to decision

K160900 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160900/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Apr 1, 2016
Decision date	May 31, 2016
Days to decision	60 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 ...