

K142873 OptiFix Fixation System - Straight 5mm X 39 cm - 30 absorbable fasteners, OptiFix Fixation System - Straight 5mm x 39 cm - 15 absorbable fasteners

Mar 12, 2015
162 days to decision

K142873 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k142873/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Oct 1, 2014
Decision date	Mar 12, 2015
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	Christine Lloyd
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 ...