

K170278 OptiFix AT Absorbable Fixation System with Articulating Technology - 30 Fasteners, OptiFix AT Absorbable Fixation System with Articulating Technology - 15 Fasteners

May 31, 2017
121 days to decision

K170278 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k170278/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jan 30, 2017
Decision date	May 31, 2017
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	KATHERINE EARLE
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 ...