

K142711 ONFLEX MeshMar 20, 2015
179 days to decisionK142711 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k142711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 22, 2014
Decision date	Mar 20, 2015
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	Mariya Buharin
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 ...
