FDA 510(k) Premarket Notification

CLEARED

K063178 BARD COLLAMEND IMPLANT, MODELS 1175102, 1175103, 1175104, 1175105, 1175106

Nov 21, 2006
33 days to decision

K063178 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k063178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Oct 19, 2006
Decision date	Nov 21, 2006
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	STEPHANIE BAKER
Website	https://www.bd.com
510(k) history	645 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 ...