

**K042949 PELVILACE TRANSOBTURATOR BIOURETHRAL
SUPPORT SYSTEM (PELVILACE TO SYSTEM)**Nov 9, 2004
14 days to decisionK042949 · Product code: **PAG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k042949/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Non-synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (PAG)
Date received	Oct 26, 2004
Decision date	Nov 9, 2004
Days to decision	14 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	JOHN C KNORPP
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 ...