FDA 510(k) Premarket Notification

K962538 BARD COAGULATING RESECTOR MODEL (3552XX

CLEARED

Dec 17, 1996
172 days to decision

K962538 · Product code: **FAS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k962538/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Jun 28, 1996
Decision date	Dec 17, 1996
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	XX=01,02,03,04,05 OR 06)

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	EVANS YI-WEN WUU
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 ...