

K003956 BARD ENDOCINCH SUTURING SYSTEM # 000452Jan 5, 2001
15 days to decisionK003956 · Product code: **ODE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k003956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Suture/plication System, Gastroesophageal Reflux Disease (gerd) (ODE)
Date received	Dec 21, 2000
Decision date	Jan 5, 2001
Days to decision	15 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	000454; 000595

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	BETH A ZIS
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 ...

REGULATORY CONSULTANT

Consulting firm	N.V. Kema
Contact	PETER N RUYS

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k003956/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026