FDA 510(k) Premarket Notification

CLEARED

K093068 FINESSE ULTRA BREAST BIOSPY SYSTEM DRIVER - BLUE, PINK, PROBE FO1BLU, FOIPNK, F14105US

Nov 10, 2009
41 days to decision

K093068 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093068/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 30, 2009
Decision date	Nov 10, 2009
Days to decision	41 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	CINDY MOSS
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	**Citech**
Contact	ROBERT MOSENKIS

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