

**K103359 FINESSE ULTRA BREAST BIOPSY SYSTEM DRIVER  
(BLUE, PINK)**Dec 27, 2010  
41 days to decisionK103359 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k103359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 16, 2010
Decision date	Dec 27, 2010
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Contact	CINDY MOSS
Website	<a href="https://www.bd.com">https://www.bd.com</a>
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 ...