CLEARED

K050006 BOREALIS AMPLIFIER (CLEARSIGN), MODEL 2001232 160 CHANNEL VERSION, 2001267 80 CHANNEL VERSION, 2001268 40 CHANNEL VERSIO

May 27, 2005
144 days to decision

K050006 · Product code: **DRQ** · Cardiovascular
Source: https://www.510kdatabase.net/k050006/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier And Signal Conditioner, Transducer Signal (DRQ)
Date received	Jan 3, 2005
Decision date	May 27, 2005
Days to decision	144 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	DEBORAH L HERRINGTON
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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k050006/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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