FDA 510(k) Premarket Notification

CLEARED

K070201 BARD INTRA-ABDOMINAL PRESSURE MONITORING DEVICE, MODEL IAP-001

Aug 1, 2007
191 days to decision

K070201 · Product code: **PHU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k070201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intra-abdominal Pressure Monitoring Device (PHU)
Date received	Jan 22, 2007
Decision date	Aug 1, 2007
Days to decision	191 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	MICHELLE GUDITH
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 ...