

K915553 USCI(R) HEMAFLEX(TM) INTRODUCER WITH COATINGFeb 21, 1992
72 days to decisionK915553 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k915553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 11, 1991
Decision date	Feb 21, 1992
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	PATRICIA W FRYDRYCK
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 ...