FDA 510(k) Premarket Notification

K904079 BARD UTERINE MANIPULATOR

CLEARED

Feb 7, 1991
155 days to decision

K904079 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k904079/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Sep 5, 1990
Decision date	Feb 7, 1991
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	ERNEST MANFREDO
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 ...