FDA 510(k) Premarket Notification

CLEARED

K192239 WavelinQ Plus EndoAVF System

Oct 17, 2019
59 days to decision

K192239 · Product code: **PQK** · Cardiovascular
Source: https://www.510kdatabase.net/k192239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter For Creation Of An Arteriovenous Fistula For Hemodialysis Access (PQK)
Date received	Aug 19, 2019
Decision date	Oct 17, 2019
Days to decision	59 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	Kulveen Dhatt
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 ...