

K182796 WavelinQ 4F EndoAVF SystemFeb 6, 2019
128 days to decisionK182796 · Product code: **PQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k182796/>**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	Oct 1, 2018
Decision date	Feb 6, 2019
Days to decision	128 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 ...

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Device record: <https://www.510kdatabase.net/k182796/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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