FDA 510(k) Premarket Notification

K973322 DIAPACT CRRT

CLEARED

Nov 10, 1998
432 days to decision

K973322 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k973322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 4, 1997
Decision date	Nov 10, 1998
Days to decision	432 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**B.Braun Medical, Inc.**
Location	Plymouth, MN, US
Contact	MARK S ALSBERGE
Website	http://www.bbraunusa.com/
510(k) history	149 submissions · 146 cleared · 1993-2026

B.Braun Medical, Inc. is a leading medical technology company specializing in infusion therapy, vascular access, and hospital-based medical devices. The company operates with a manufacturing facility in Plymouth, Massachusetts. B.Braun Medical has maintained a strong FDA 510(k) regulatory record since 1993. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2025 demonstrate continued innovation in infusion pumps, IV catheters, and administration sets for general hospital use. The company's cleared device portfolio focuses on smart ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k973322/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026