

K955179 CONTRAST MEDIA SETMar 12, 1997
485 days to decisionK955179 · Product code: IZI · Radiology
Source: <https://www.510kdatabase.net/k955179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Nov 13, 1995
Decision date	Mar 12, 1997
Days to decision	485 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	148 submissions · 145 cleared · 1993-2025

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 ...
