

**K952435 CELSITE PEDIATRIC VENOUS SYSTEM**Apr 17, 1996  
329 days to decisionK952435 · Product code: **LJT** · General Hospital  
Source: <https://www.510kdatabase.net/k952435/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	May 24, 1995
Decision date	Apr 17, 1996
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>B.Braun Medical, Inc.</b>
Location	Plymouth, MN, US
Contact	MARK S ALSBBRGE
Website	<a href="http://www.bbraunusa.com/">http://www.bbraunusa.com/</a>
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 ...

---