

**K150800 Valved Safety Centesis Catheter**Nov 12, 2015  
231 days to decisionK150800 · Product code: **GCB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k150800/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Catheter (GCB)
Date received	Mar 26, 2015
Decision date	Nov 12, 2015
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---