

K150787 Universal SpikeDec 2, 2015
252 days to decisionK150787 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k150787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Mar 25, 2015
Decision date	Dec 2, 2015
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B.Braun Medical, Inc.
Location	Plymouth, MN, US
Contact	Tracy Maddock
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 ...
