

K170897 Surecan Safety II Needle, Surecan Safety II Needle, Surecan Safety II Needle with Caresite Luer Access Device and Y site

Nov 3, 2017
221 days to decision

K170897 · Product code: PTI · General Hospital
Source: <https://www.510kdatabase.net/k170897/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-coring (huber) Needle (PTI)
Date received	Mar 27, 2017
Decision date	Nov 3, 2017
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B.Braun Medical, Inc.
Location	Plymouth, MN, US
Contact	Angela J. Caravella
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 ...