FDA 510(k) Premarket Notification

K131842 STERICAN CANNULA

CLEARED

Aug 20, 2013
60 days to decision

K131842 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k131842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 21, 2013
Decision date	Aug 20, 2013
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**B.Braun Medical, Inc.**
Location	Plymouth, MN, US
Contact	KIMBERLY SMITH
Website	http://www.bbraunusa.com/
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 ...