FDA 510(k) Premarket Notification

K031923 ULTRASITE VALVE

CLEARED

Aug 11, 2003
49 days to decision

K031923 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k031923/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jun 23, 2003
Decision date	Aug 11, 2003
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**B.Braun Medical, Inc.**
Location	Plymouth, MN, US
Contact	SHERI L MUSGNUNG
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 ...