

**K161623 Prontosan Wound Irrigation Solution, 40 mL,
Prontosan Wound Irrigation Solution, 350 mL, Prontosan
Wound Irrigation Solution, 1000 mL**Nov 10, 2016
150 days to decisionK161623 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jun 13, 2016
Decision date	Nov 10, 2016
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B.Braun Medical, Inc.
Location	Plymouth, MN, US
Contact	Nancy Skocypec
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 ...