

K101882 PRONTOSAN ANTIMICROBIAL WOUND GELNov 3, 2010
120 days to decisionK101882 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k101882/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Jul 6, 2010 |
| Decision date | Nov 3, 2010 |
| Days to decision | 120 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | B.Braun Medical, Inc. |
| Location | Plymouth, MN, US |
| Contact | MATTHEW J HOMA |
| 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 ...
