FDA 510(k) Premarket Notification

CLEARED

K161552 0.9% Sodium Chloride Injection, USP BD PosiFlush SP Syringe

Feb 2, 2017
241 days to decision

K161552 · Product code: **NGT** · General Hospital
Source: https://www.510kdatabase.net/k161552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Saline, Vascular Access Flush (NGT)
Date received	Jun 6, 2016
Decision date	Feb 2, 2017
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Becton, Dickinson and Company**
Location	Franklin Lakes, NJ, US
Contact	John Blewitt
Website	https://www.bd.com
510(k) history	134 submissions · 134 cleared · 2010-2026

Becton, Dickinson and Company is an American multinational medical technology company headquartered in Franklin Lakes, New Jersey. BD manufactures and sells medical devices, instrument systems, and reagents globally. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions spanning 2010 to 2026. BD's cleared devices span multiple categories including microbiology systems, blood collection products, and general hospital devices. The company's latest clearance in 2026 reflects continued innovation and regulatory engagemen...