FDA 510(k) Premarket Notification

CLEARED

K231161 0.9% Sodium Chloride Injection, USP BD PosiFlush™ SF Saline Flush Syringe

Jul 21, 2023
88 days to decision

K231161 · Product code: **NGT** · General Hospital
Source: https://www.510kdatabase.net/k231161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saline, Vascular Access Flush (NGT)
Date received	Apr 24, 2023
Decision date	Jul 21, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Becton, Dickinson and Company**
Location	Franklin Lakes, NJ, US
Contact	Samhitha Mohan
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...