FDA 510(k) Premarket Notification

CLEARED

K162081 BD 1ml Luer-lok Hypodermic Syringe, BD 1 mL Luer-Lok Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse Hypodermic Needle, BD 1ml Luer-lok Insulin Syringe

Dec 19, 2016
145 days to decision

K162081 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k162081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jul 27, 2016
Decision date	Dec 19, 2016
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Becton, Dickinson and Company**
Location	Franklin Lakes, NJ, US
Contact	Murtaza Rana
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...