

K182589 BD Plastipak SyringeMar 14, 2019
175 days to decisionK182589 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k182589/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 20, 2018
Decision date	Mar 14, 2019
Days to decision	175 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson and Company
Location	Franklin Lakes, NJ, US
Contact	Leslie Robinson-Frye
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 engagement...

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