

# K250853 Merit Syringe

Nov 4, 2025  
228 days to decision

K250853 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k250853/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Mar 21, 2025
Decision date	Nov 4, 2025
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Merit Medical Systems, Inc.</b>
Location	South Jordan, UT, US
Contact	Kirk McIntosh
Website	<a href="https://www.merit.com">https://www.merit.com</a>
510(k) history	177 submissions · 169 cleared · 1988-2026

Merit Medical Systems, Inc. is a leading manufacturer of disposable medical devices for interventional, diagnostic, and therapeutic procedures. Based in South Jordan, the company serves hospitals and physicians worldwide. Merit Medical has established a strong FDA 510(k) regulatory record since its first clearance in 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances span cardiovascular devices, neurology, gastroenterology, and general surgery, demonstrating broad clinical expertise. The latest clearance in 2026 confirms the com...