FDA 510(k) Premarket Notification

K182216 Merit Syringe

CLEARED

Nov 6, 2018
83 days to decision

K182216 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k182216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Syringe, Piston (FMF)
Date received	Aug 15, 2018
Decision date	Nov 6, 2018
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Merit Medical Systems, Inc.**
Location	South Jordan, UT, US
Contact	John Skousen
Website	https://www.merit.com
510(k) history	178 submissions · 170 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...