

K163084 Merit Coronary Control SyringeJun 15, 2017
224 days to decisionK163084 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k163084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 3, 2016
Decision date	Jun 15, 2017
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems, Inc.
Location	South Jordan, UT, US
Contact	Cory Marsh
Website	https://www.merit.com
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163084/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026