

**K011811 MONARCH INFLATION SYRINGE**Aug 22, 2001  
72 days to decisionK011811 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k011811/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jun 11, 2001
Decision date	Aug 22, 2001
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary
Other names	UNIVERSAL FLUID DISPENSING SYRINGE

**APPLICANT**

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Company	<b>Merit Medical Systems, Inc.</b>
Location	South Jordan, UT, US
Contact	DAN REIGLE
Website	<a href="https://www.merit.com">https://www.merit.com</a>
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...