

**K242229 Micro Ace Gold Advanced Micro Access System**Jan 15, 2025  
169 days to decisionK242229 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242229/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jul 30, 2024
Decision date	Jan 15, 2025
Days to decision	169 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	Niloufar Samimi
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...