

K943597 MONARCH AP(TM)Feb 10, 1995
202 days to decisionK943597 · Product code: **MAV** · Cardiovascular
Source: <https://www.510kdatabase.net/k943597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Balloon Inflation (MAV)
Date received	Jul 23, 1994
Decision date	Feb 10, 1995
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems, Inc.
Location	South Jordan, UT, US
Contact	DENNIS REIGLE
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...
