FDA 510(k) Premarket Notification

K884913 MERIT INTELLIFLATOR(TM) & MERIT MONITOR(TM)

CLEARED

Apr 18, 1989
141 days to decision

K884913 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k884913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 28, 1988
Decision date	Apr 18, 1989
Days to decision	141 days
Third-party review	No

APPLICANT

Company	**Merit Medical Systems, Inc.**
Location	South Jordan, UT, US
Contact	FRED LAMPROPOULOS
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...