

K883718 MERIT HI-FLEX(TM)Jan 30, 1989
152 days to decisionK883718 · Product code: **FPK** · General Hospital
Source: <https://www.510kdatabase.net/k883718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Fluid Delivery (FPK)
Date received	Aug 31, 1988
Decision date	Jan 30, 1989
Days to decision	152 days
Third-party review	No

APPLICANT

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