FDA 510(k) Premarket Notification

CLEARED

K073035 PRELUDE AND PRELUDE PRO SHEATH INTRODUCERS

Nov 20, 2007
22 days to decision

K073035 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k073035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Oct 29, 2007
Decision date	Nov 20, 2007
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Merit Medical Systems, Inc.**
Location	South Jordan, UT, US
Contact	SHIRLEY HYINK
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...