

K262086 PreludeSYNC™ Radial Compression Device

Jul 22, 2026
30 days to decision

K262086 · Product code: DXC · Cardiovascular
Source: <https://www.510kdatabase.net/k262086/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Clamp, Vascular (DXC)
Date received	Jun 22, 2026
Decision date	Jul 22, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems, Inc.
Location	South Jordan, UT, US
Contact	Frank Sauz
Website	https://www.merit.com
510(k) history	180 submissions · 172 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...