

**K100319 MERIT MANIFOLD WITH INTEGRATED TRANSDUCER,
MODEL 203LTCHN-R**Apr 28, 2010
83 days to decisionK100319 · Product code: DTL · Cardiovascular
Source: <https://www.510kdatabase.net/k100319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Feb 4, 2010
Decision date	Apr 28, 2010
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary
Other names	503LTCHN-R; 203LTPHN-R; 203LTCHWN-R; 503LTCHWN-R; 203L

APPLICANT

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