

K140382 AEROMINI TRACHEOBRONCHIAL STENT TECHNOLOGYNov 25, 2014
284 days to decisionK140382 · Product code: JCT · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k140382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Tracheal, Expandable (JCT)
Date received	Feb 14, 2014
Decision date	Nov 25, 2014
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k140382/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 5, 2026