

K212675 Aspira Peritoneal Drainage System

Dec 14, 2021
112 days to decisionK212675 · Product code: **PNG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212675/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Peritoneal, Drainage Catheter For Refractory Ascites, Long-term Indwelling (PNG)
Date received	Aug 24, 2021
Decision date	Dec 14, 2021
Days to decision	112 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	Jennifer Webb
Website	https://www.merit.com
510(k) history	177 submissions · 169 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...

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Device record: <https://www.510kdatabase.net/k212675/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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