

**K093947 ALIMAXX-B UNCOVERED BILIARY STENT SYSTEM  
ENDOSCOPIC**Jan 21, 2010  
29 days to decisionK093947 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k093947/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 23, 2009
Decision date	Jan 21, 2010
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Merit Medical Systems, Inc.</b>
Location	South Jordan, UT, US
Contact	CAROL HOLLOWAY, RAC
Website	<a href="https://www.merit.com">https://www.merit.com</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k093947/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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