

**K063733 RESOLVE BILIARY DRAINAGE CATHETER**Nov 14, 2007  
331 days to decisionK063733 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k063733/>**SUBMISSION DETAILS**

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|                       |                                                         |
|-----------------------|---------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional                                             |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received         | Dec 18, 2006                                            |
| Decision date         | Nov 14, 2007                                            |
| Days to decision      | 331 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        | AMY MCKINNEY                                              |
| 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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