

**K250409 Disposable Balloon Catheter (B5-2Q)**Oct 21, 2025  
250 days to decisionK250409 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250409/>**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	Feb 13, 2025
Decision date	Oct 21, 2025
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Disposable Balloon Catheter (B7-2Q); Disposable Balloon Catheter (B7-2LA)

**APPLICANT**

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Company	<b>Olympus Medical Systems Corporation</b>
Location	Melville, NY, US
Contact	Eve Smith
510(k) history	81 submissions · 81 cleared · 2004-2026

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