

**K955413 ENDOVATIONS TRIPLE LUMEN BALLOON  
DILATATION CATHETER**Feb 8, 1996  
73 days to decisionK955413 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k955413/>**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	Nov 27, 1995
Decision date	Feb 8, 1996
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Endovations</b>
Location	Camp Hill, PA, US
Contact	RONALD D WOLFE
510(k) history	37 submissions · 36 cleared · 1986-1996

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