

**K050502 SINGLE USE BALLOON DILATOR MAXPASSTM**Jul 8, 2005  
130 days to decisionK050502 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k050502/>**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 28, 2005
Decision date	Jul 8, 2005
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Winter &amp; Ibe GmbH</b>
Location	Melville, NY, US
Contact	LAURA STORMS-TYLER
510(k) history	43 submissions · 43 cleared · 1997-2026

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