

**K935094 BALLOON DILATION CATHETER**Jan 24, 1995  
459 days to decisionK935094 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k935094/>**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	Oct 22, 1993
Decision date	Jan 24, 1995
Days to decision	459 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Wilson-Cook Medical, Inc.</b>
Location	Winstrom-Salem, NC, US
Contact	PAULA A JOYCE
510(k) history	125 submissions · 118 cleared · 1985-2026

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