

**K965067 DILATION CATHETER, BALLOON**Jan 28, 1997  
41 days to decisionK965067 · Product code: **GBM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k965067/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Dec 18, 1996
Decision date	Jan 28, 1997
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	CAROL J HALLOWAY
Website	<a href="https://www.bostonscientific.com/">https://www.bostonscientific.com/</a>
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...