

K011909 ULTRA-THIN SDS BALLOON DILATATION CATHETERNov 28, 2001
162 days to decisionK011909 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k011909/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 19, 2001
Decision date	Nov 28, 2001
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	JENNIFER BOLTON
Website	https://www.bostonscientific.com/
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...

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Device record: <https://www.510kdatabase.net/k011909/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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