

**K191446 Ureteral Stent Systems, Biliary Drainage Catheters**Jan 2, 2020  
216 days to decisionK191446 · Product code: **FAD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k191446/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	May 31, 2019
Decision date	Jan 2, 2020
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Jois Zuniga Gamboa
Website	<a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a>
510(k) history	231 submissions · 218 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k191446/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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