

## K172929 Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set, and Clear Renal Sheath

Jan 10, 2018  
107 days to decisionK172929 · Product code: LJE · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k172929/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Sep 25, 2017
Decision date	Jan 10, 2018
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Daniel FitzDaniel
Website	<a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a>
510(k) history	229 submissions · 216 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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