

**K180068 ORISE Gel**Sep 28, 2018  
262 days to decisionK180068 · Product code: **PLL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k180068/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Submucosal Injection Agent (PLL)
Date received	Jan 9, 2018
Decision date	Sep 28, 2018
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific</b>
Location	San Jose, CA, US
Contact	Thomas Hirte
Website	<a href="http://www.bostonscientific.com/">http://www.bostonscientific.com/</a>
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...