

**K211960 Agile Esophageal OTW Stent System**Nov 22, 2021  
151 days to decisionK211960 · Product code: **ESW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k211960/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Jun 24, 2021
Decision date	Nov 22, 2021
Days to decision	151 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	Inderdeep Tiwana
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...