

**K191538 Resectr Tissue Resection Device**Jan 16, 2020  
220 days to decisionK191538 · Product code: **HIH** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k191538/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jun 10, 2019
Decision date	Jan 16, 2020
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Brooke Cuddy
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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