

**K202224 SpaceOAR System**Aug 28, 2020  
21 days to decisionK202224 · Product code: **OVB** · Radiology  
Source: <https://www.510kdatabase.net/k202224/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hydrogel Spacer (OVB)
Date received	Aug 7, 2020
Decision date	Aug 28, 2020
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Jeanne OToole
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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