

**K052302 HEMASHIELD PLATINUM WOVEN DOUBLE VELOUR  
TAAA GRAFT CONFIGURATION**Sep 12, 2005  
19 days to decisionK052302 · Product code: **MAL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k052302/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Graft, Vascular, Synthetic/biologic Composite (MAL)
Date received	Aug 24, 2005
Decision date	Sep 12, 2005
Days to decision	19 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	JENNIFER BOLTON
Website	<a href="https://www.bostonscientific.com/">https://www.bostonscientific.com/</a>
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...