

**K152403 Permanent Sled Bag**Sep 22, 2015  
28 days to decisionK152403 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k152403/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Aug 25, 2015
Decision date	Sep 22, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific</b>
Location	San Jose, CA, US
Contact	George J. Prendergast
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. ...

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