

**K051361 EASY CORE DETACHABLE BIOPSY SYSTEM**Jun 16, 2005  
22 days to decisionK051361 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k051361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	May 25, 2005
Decision date	Jun 16, 2005
Days to decision	22 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	CHRISTINE M CAMERON
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...