

# K223616 Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device

Dec 30, 2022  
25 days to decisionK223616 · Product code: **ODG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k223616/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Dec 5, 2022
Decision date	Dec 30, 2022
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Kyra McNamara
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...