

K100712 RESOUND ENDOSCOPIC ULTRASOUND ASPIRATION NEEDLEMar 30, 2010
18 days to decisionK100712 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k100712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Mar 12, 2010
Decision date	Mar 30, 2010
Days to decision	18 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	ASHLEY PYLE
Website	https://www.bostonscientific.com
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...