

**K063493 I REVIEW SOFTWARE(ACCESSORY TO) ILAB
ULTRASOUND IMAGING SYSTEM) VERSION1.0**Dec 21, 2006
31 days to decisionK063493 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k063493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 20, 2006
Decision date	Dec 21, 2006
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	CHRISTINE DUNBAR
Website	https://www.bostonscientific.com/
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...

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Device record: <https://www.510kdatabase.net/k063493/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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