

K982840 BSC SONICATH ULTRA INTRAVASCULAR ULTRASOUND IMAGING WIRE WITH DETACHABLE ADAPTER & BSC SONICATH ULTRA ULTRASOUND IMAGING

Nov 9, 1998
89 days to decision

K982840 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k982840/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 12, 1998
Decision date	Nov 9, 1998
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	DONNA K TEMPLEMAN
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...