

**K041818 SONICATH ULTRA IMAGING CATHETER 3.2F 20MHZ,  
MODELS 37410/456221/C1020**Nov 10, 2004  
127 days to decisionK041818 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k041818/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jul 6, 2004
Decision date	Nov 10, 2004
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	ROBERT Z PHILLIPS
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k041818/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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