

K200733 Opticross 35 15 MHz Peripheral Imaging CatheterApr 17, 2020
28 days to decisionK200733 · Product code: **ITX** · Cardiovascular
Source: <https://www.510kdatabase.net/k200733/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Mar 20, 2020
Decision date	Apr 17, 2020
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Jennifer L. Foley
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...

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