

K153617 OptiCross 6, 40 MHz Coronary Imaging Catheter (US Distribution), OptiCross 6, 40 MHz Coronary Imaging Catheter (EU Distribution), OptiCross 6, 40 MHz Coronary Imaging Catheter (Intercontinental Distribution)Feb 25, 2016
69 days to decisionK153617 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k153617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Dec 18, 2015
Decision date	Feb 25, 2016
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Eric Elliott
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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