

K260816 OptiCross Coronary Imaging Catheter (H749518110)

Apr 8, 2026
26 days to decision

K260816 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k260816/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Mar 13, 2026
Decision date	Apr 8, 2026
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OptiCross 6 Coronary Imaging Catheter (H7495181160); OptiCross HD Coronary Imaging Catheter (H74939352040); OptiCross 6 HD Coronary Imaging Catheter (H74939354080); OptiCross Coronary Imaging Catheter (Bagless) (H749518130); OptiCross 6 Coronary Imaging Catheter (Bagless) (H7495181360); OptiCross HD Coronary Imaging Catheter (Bagless) (H74939352050); OptiCross 6 HD Coronary Imaging Catheter (Bagless) (H74939354090)

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	Brian Li
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...