

K152605 Impulse Angiographic Catheter, Expo Angiographic Catheter

Oct 29, 2015
48 days to decisionK152605 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k152605/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Intravascular, Diagnostic (DQO) |
| Date received | Sep 11, 2015 |
| Decision date | Oct 29, 2015 |
| Days to decision | 48 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------------------------------------------------|
| Company | Boston Scientific Corporation |
| Location | Marlborough, MA, US |
| Contact | MAC MCKEEN |
| 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152605/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026