

K180864 WATCHMAN TruSeal Access SystemJul 20, 2018
109 days to decisionK180864 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k180864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 2, 2018
Decision date	Jul 20, 2018
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	Nikki M Ibis
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. ...

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