

**K201178 iLab Polaris Multi-Modality Guidance System**May 29, 2020  
28 days to decisionK201178 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k201178/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Special                                  |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received         | May 1, 2020                              |
| Decision date         | May 29, 2020                             |
| Days to decision      | 28 days                                  |
| Third-party review    | No                                       |
| Combination product   | No                                       |
| PCCP authorized       | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Boston Scientific</b>  |
| Location       | San Jose, CA, US  |
| Contact        | Kevin Lam   |
| Website        | <a href="http://www.bostonscientific.com/">http://www.bostonscientific.com/</a> |
| 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. ...