

**K230051 14F iSLEEVE™ Introducer Set**Feb 3, 2023  
28 days to decisionK230051 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k230051/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Introducer, Catheter (DYB)         |
| Date received         | Jan 6, 2023                        |
| Decision date         | Feb 3, 2023                        |
| 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 Corporation</b>  |
| Location       | Marlborough, MA, US   |
| Contact        | Kendall Lindenman   |
| Website        | <a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a> |
| 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...