

K223824 POLARSHEATH™ Steerable Sheath 12F (UPN:M004CRBS3150), POLARMAP™ Circular Mapping Catheter (UPN:M004CRBS7210), POLARMAP™ EP Electrical Cable (UPN:M004CRBS62000), SMARTFREEZE™ Esophageal Temperature Sensor (ETS) Cable: -SMARTFREEZE™ Esophageal Temperature Sensor (ETS) Cable (UPN: M004CRBS6310), -SMARTFREEZE™ 16 PIN Esophageal Temperature Sensor (ETS) Cable (UPN: M004CRBS6320), -SMARTFREEZE™ CIRCA Esophageal Temperature Sensor (ETS) Cable (UPN: M004CRBS6340), SMARTFREEZE™ Pressure Sensor

Mar 22, 2023
91 days to decision

K223824 · Product code: **DRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k223824/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Steerable (DRA) |
| Date received | Dec 21, 2022 |
| Decision date | Mar 22, 2023 |
| Days to decision | 91 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Corporation |
| Location | Marlborough, MA, US |
| Contact | Derek Charchuk |
| 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...