

K243245 IceSeed 1.5 CX Straight Needle (H7493968333170)Oct 18, 2024
7 days to decisionK243245 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243245/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Unit, Cryosurgical, Accessories (GEH) |
| Date received | Oct 11, 2024 |
| Decision date | Oct 18, 2024 |
| Days to decision | 7 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | IceSphere1.5 CX Straight Needle (H7493968435730); IceRod 1.5 CX Straight Needle (H7493968535330) |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Corp |
| Location | San Jose, CA, US |
| Contact | Dana Borris |
| Website | https://www.bostonscientific.com/ |
| 510(k) history | 432 submissions · 411 cleared · 1988-2024 |

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...