

K232635 IceSeed 1.5 CX 90° Needle (H7493967433170)Nov 22, 2023
84 days to decisionK232635 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Aug 30, 2023
Decision date	Nov 22, 2023
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	IceSeed 1.5 CX S 90° Needle (H7493967233100)

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	Jake Burke
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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