

K230551 Visual-ICE Cryoablation SystemAug 8, 2023
161 days to decisionK230551 · Product code: **GEH** · Orthopedic
Source: <https://www.510kdatabase.net/k230551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Feb 28, 2023
Decision date	Aug 8, 2023
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Amy McKinney
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...

CLINICAL EVIDENCE - NCT02511678**Multicenter Study of Cryoablation for Palliation of Painful Bone Metastases**

Status	Completed
Enrollment	73 patients (actual)
Study sites	11 sites
Condition studied	Pain; Neoplasm Metastasis; Bone Metastasis of Diverse Origins
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 12, 2018
Sponsor	Boston Scientific Corporation (Industry)

Primary outcome

Change From Baseline in Worst Pain Scores as Assessed by the Brief Pain Inventory-Short Form (BPI-SF) at Week 8

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02511678