FDA 510(k) Premarket Notification

**CLEARED**

# K234002 ICEfx Cryoablation System (FPRCH8000-02)

Mar 13, 2024
85 days to decision

K234002 · Product code: **GEH** · Orthopedic
Source: https://www.510kdatabase.net/k234002/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Cryosurgical, Accessories (GEH) |
| Date received | Dec 19, 2023 |
| Decision date | Mar 13, 2024 |
| Days to decision | 85 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

**APPLICANT**

| | |
|---|---|
| Company | **Boston Scientific** |
| Location | San Jose, CA, US |
| Contact | Benjamin Van Santen |
| 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. ...