FDA 510(k) Premarket Notification

# K252661 SternaFuse Ti Fixation System

**CLEARED**

Nov 19, 2025
89 days to decision

K252661 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k252661/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Aug 22, 2025 |
| Decision date | Nov 19, 2025 |
| Days to decision | 89 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Fusion Innovations, LLC** |
| Location | Rock Hill, SC, US |
| Contact | Adam Cowick |
| 510(k) history | 2 submissions · 2 cleared · 2022-2025 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Rook Quality Systems** |
| Contact | Sarah Robbins |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov