

K242671 Treace Medical Concepts (TMC) Screw Fixation System

Oct 4, 2024
28 days to decisionK242671 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k242671/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Sep 6, 2024 |
| Decision date | Oct 4, 2024 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Treace Medical Concepts, Inc. |
| Location | Ponte Vedra, FL, US |
| Contact | Melissa Coloroso |
| 510(k) history | 15 submissions · 15 cleared · 2015-2026 |

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