

K221181 Treace Medical Concepts (TMC) Plating SystemJan 5, 2023
255 days to decisionK221181 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k221181/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Apr 25, 2022 |
| Decision date | Jan 5, 2023 |
| Days to decision | 255 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026