

K213572 JuniOrtho Plating System™Jan 18, 2022
69 days to decisionK213572 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k213572/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Nov 10, 2021 |
| Decision date | Jan 18, 2022 |
| Days to decision | 69 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Orthofix Srl |
| Location | Rockville, MD, US |
| Contact | Gianluca Ricadona |
| 510(k) history | 36 submissions · 36 cleared · 1995-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------|
| Consulting firm | Wagoner Consulting Llg |
| Contact | Cheryl Wagoner |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213572/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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