

K252600 Pediatric Plating Platform I Small-MiniOct 9, 2025
52 days to decisionK252600 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k252600/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Aug 18, 2025 |
| Decision date | Oct 9, 2025 |
| Days to decision | 52 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------------------------------------------|
| Company | OrthoPediatrics Corp. |
| Location | Warsaw, IN, US |
| Contact | Yan Li |
| Website | https://www.orthopediatrics.com |
| 510(k) history | 40 submissions · 38 cleared · 2008-2026 |

OrthoPediatrics Corp. is a pediatric orthopedic medical device company focused exclusively on children's orthopedic care. Based in Warsaw, Indiana, the company designs and manufactures implants and surgical systems for pediatric trauma, deformity correction, scoliosis, and sports medicine applications. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. 100% of submissions fall within the Orthopedic device category. The latest clearance in 2026 reflects continued regulatory activity and product innovation in pediatric o...