FDA 510(k) Premarket Notification

**CLEARED**

# K201259 ORTHOLOC 2 with 3Di Technology Pilon Fracture Plating System

Jan 8, 2021
242 days to decision

K201259 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k201259/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | May 11, 2020 |
| Decision date | Jan 8, 2021 |
| Days to decision | 242 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Wrightmedicaltechnologyinc** |
| Location | Arlington, TN, US |
| Contact | Anna Hinton |
| 510(k) history | 302 submissions · 291 cleared · 1993-2023 |