

K210653 ONE Planner HipJul 7, 2021
125 days to decisionK210653 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k210653/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Mar 4, 2021 |
| Decision date | Jul 7, 2021 |
| Days to decision | 125 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Orthosoft D/B/A Zimmer Cas |
| Location | Montreal, CA |
| Contact | Paul Hardy |
| 510(k) history | 7 submissions · 7 cleared · 2021-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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