

K201430 InFrame™ Cannulated Fixation SystemJun 20, 2020
19 days to decisionK201430 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k201430/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Jun 1, 2020 |
| Decision date | Jun 20, 2020 |
| Days to decision | 19 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Exsomed Corp. |
| Location | Aliso Viejo, CA, US |
| Contact | Jung Chang |
| 510(k) history | 2 submissions · 2 cleared · 2020-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201430/> 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 27, 2026