

K251569 Bone ScrewAug 13, 2025
83 days to decisionK251569 · Product code: **DZL** · DentalSource: <https://www.510kdatabase.net/k251569/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Intraosseous (DZL) |
| Date received | May 22, 2025 |
| Decision date | Aug 13, 2025 |
| Days to decision | 83 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osstem Implant Co., Ltd. |
| Location | Busan, KR |
| Contact | Kang Seungju |
| Website | https://www.osstem.com |
| 510(k) history | 68 submissions · 68 cleared · 2006-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------|
| Consulting firm | Hiossen, Inc. |
| Contact | Mateusz Leszczak |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251569/> 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 14, 2026