

**K151195 OsteoMed IMF Screw**Sep 21, 2015  
140 days to decisionK151195 · Product code: **DZL** · Dental  
Source: <https://www.510kdatabase.net/k151195/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	May 4, 2015
Decision date	Sep 21, 2015
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Osteomed</b>
Location	Addison, TX, US
Contact	Piedad Pena
510(k) history	12 submissions · 12 cleared · 2012-2021

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151195/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026