

**K200386 Z5-BL**Oct 14, 2020  
239 days to decisionK200386 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k200386/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 18, 2020
Decision date	Oct 14, 2020
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Z-Systems AG</b>
Location	San Diego, CA, US
Contact	Rubino DiGirolamo
510(k) history	9 submissions · 9 cleared · 2007-2021

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200386/> 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