

**K190243 Z5-BL**Jan 3, 2020  
331 days to decisionK190243 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k190243/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 6, 2019
Decision date	Jan 3, 2020
Days to decision	331 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190243/> 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