

**K220022 TRATE Dental Implant System**Apr 4, 2022  
89 days to decisionK220022 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k220022/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 5, 2022
Decision date	Apr 4, 2022
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trate AG</b>
Location	B?ch, CH
Contact	Vladlena Shulezhko
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sigma Biomedical</b>
Contact	Jorge Millan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220022/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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