

**K191256 Straumann BLX Ø3.5 mm Implants**Dec 27, 2019  
231 days to decisionK191256 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k191256/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 10, 2019
Decision date	Dec 27, 2019
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Institut Straumann AG</b>
Location	Basel, CH
Contact	Ana C. M. Vianna
Website	<a href="https://www.straumann.com">https://www.straumann.com</a>
510(k) history	90 submissions · 90 cleared · 1990-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Straumann USA, LLC</b>
Contact	Jennifer M. Jackson

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

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