

**K213063 TLX SRAs and TLX Gold Abutments**Apr 8, 2022  
197 days to decisionK213063 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k213063/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 23, 2021
Decision date	Apr 8, 2022
Days to decision	197 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	Gina Chang
Website	<a href="https://www.straumann.com">https://www.straumann.com</a>
510(k) history	88 submissions · 88 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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