

K203355 Straumann TLX Novaloc and Cementable AbutmentsFeb 12, 2021
88 days to decisionK203355 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k203355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Nov 16, 2020
Decision date	Feb 12, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Institut Straumann AG
Location	Basel, CH
Contact	Laure Kuhner Borsenberger
Website	https://www.straumann.com
510(k) history	88 submissions · 88 cleared · 1990-2026

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
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)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203355/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026