

K201051 Straumann BoneCeramicSep 24, 2020
156 days to decisionK201051 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k201051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Apr 21, 2020
Decision date	Sep 24, 2020
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Institut Straumann AG
Location	Basel, CH
Contact	Christelle Gerspach-Gasser
Website	https://www.straumann.com
510(k) history	90 submissions · 90 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)

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