

K180477 Straumann PURE Ceramic Implant SystemJan 4, 2019
316 days to decisionK180477 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k180477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 22, 2018
Decision date	Jan 4, 2019
Days to decision	316 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Institut Straumann AG
Location	Basel, CH
Contact	Pierre-Yves Calinon
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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