

K241391 Straumann® PURE Ceramic ImplantsDec 10, 2024
209 days to decisionK241391 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k241391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 15, 2024
Decision date	Dec 10, 2024
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
Contact	Jennifer 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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