FDA 510(k) Premarket Notification

K191256 Straumann BLX Ø3.5 mm Implants

CLEARED

Dec 27, 2019
231 days to decision

K191256 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k191256/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 10, 2019
Decision date	Dec 27, 2019
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Institut Straumann AG**
Location	Basel, CH
Contact	Ana C. M. Vianna
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