FDA 510(k) Premarket Notification

K173594 Straumann cerabone

CLEARED

Oct 19, 2018
332 days to decision

K173594 · Product code: **NPM** · Dental
Source: https://www.510kdatabase.net/k173594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Animal Source (NPM)
Date received	Nov 21, 2017
Decision date	Oct 19, 2018
Days to decision	332 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