FDA 510(k) Premarket Notification

K190082 Straumann BLX Variobase Abutment

CLEARED

Apr 17, 2019
90 days to decision

K190082 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k190082/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jan 17, 2019
Decision date	Apr 17, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Institut Straumann AG**
Location	Basel, CH
Contact	Viviana Horhoiu
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