FDA 510(k) Premarket Notification

CLEARED

K222836 Straumann® Variobase® Abutments and Straumann® n!ce® Zirconia discs

May 15, 2023
237 days to decision

K222836 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k222836/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 20, 2022
Decision date	May 15, 2023
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Institut Straumann AG**
Location	Basel, CH
Contact	Dr. Renate Reiss
Website	https://www.straumann.com
510(k) history	88 submissions · 88 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