FDA 510(k) Premarket Notification

K220878 Straumann TLX Variobase C

CLEARED

Jun 16, 2022
83 days to decision

K220878 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k220878/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Mar 25, 2022
Decision date	Jun 16, 2022
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Institut Straumann AG**
Location	Basel, CH
Contact	Gordon Dodds
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