FDA 510(k) Premarket Notification

K243478 Straumann InLab Validated Workflow

CLEARED

Feb 19, 2025
103 days to decision

K243478 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k243478/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Nov 8, 2024
Decision date	Feb 19, 2025
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Institut Straumann AG**
Location	Basel, CH
Contact	Olivier Russo
Website	https://www.straumann.com
510(k) history	88 submissions · 88 cleared · 1990-2026

REGULATORY CONSULTANT

Consulting firm	**Straumann USA, LLC**
Contact	Jennifer Jackson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov