FDA 510(k) Premarket Notification

K033922 MODIFICATION TO ITI DENTAL IMPLANT SYSTEM

CLEARED

Jan 7, 2004
20 days to decision

K033922 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k033922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 18, 2003
Decision date	Jan 7, 2004
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Institut Straumann AG**
Location	Basel, CH
Contact	CAROLYN BITETTI
Website	https://www.straumann.com
510(k) history	90 submissions · 90 cleared · 1990-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k033922/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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