FDA 510(k) Premarket Notification

K013798 PROSTHETIC ACCESSORIES TO THE ITI DENTAL IMPLANT SYSTEM

CLEARED

Dec 19, 2001
34 days to decision

K013798 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k013798/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 15, 2001
Decision date	Dec 19, 2001
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Institut Straumann AG**
Location	Basel, CH
Contact	LINDA JALBERT
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/k013798/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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