FDA 510(k) Premarket Notification

K941393 ITI ANGLED ABUTMENT

CLEARED

Jun 14, 1995
449 days to decision

K941393 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k941393/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 22, 1994
Decision date	Jun 14, 1995
Days to decision	449 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**The Straumann Co.**
Location	Cambridge, MA, US
Contact	CAROLYN B ITETTI
510(k) history	14 submissions · 14 cleared · 1992-2004

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k941393/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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