FDA 510(k) Premarket Notification

K090260 MODIFICATION TO:STRAUMANN GUIDED INSTRUMENTS

CLEARED

Feb 26, 2009
23 days to decision

K090260 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k090260/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 3, 2009
Decision date	Feb 26, 2009
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Straumann Manufacturing, Inc.**
Location	Andover, MA, US
Contact	ELAINE ALAN
510(k) history	4 submissions · 4 cleared · 2007-2009