FDA 510(k) Premarket Notification

K973521 VARIABLE PARALLEL PIN

CLEARED

Nov 20, 1997
64 days to decision

K973521 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k973521/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 17, 1997
Decision date	Nov 20, 1997
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sulzer Calcitek, Inc.**
Location	Carlsbad, CA, US
Contact	FOSTER BOOP
510(k) history	9 submissions · 9 cleared · 1997-2001