FDA 510(k) Premarket Notification

K962106 SPLINE DENTAL IMPLANT SYSTEMS

CLEARED

Aug 29, 1996
90 days to decision

K962106 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k962106/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 31, 1996
Decision date	Aug 29, 1996
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Calcitek, Inc.**
Location	Walker, MI, US
Contact	DONNA K HOWARD
510(k) history	21 submissions · 21 cleared · 1984-1997