

K946345 INTEGRAL VIII BIOINTEGRATED DENTAL IMPLANT SYSTEMNov 15, 1995
320 days to decisionK946345 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k946345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 30, 1994
Decision date	Nov 15, 1995
Days to decision	320 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Calcitek, Inc.
Location	Walker, MI, US
Contact	CAROL WHITE
510(k) history	21 submissions · 21 cleared · 1984-1997

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