

**K946319 INTEGRAL VII 4.9MM BIOINTEGRATED DENTAL  
IMPLANT SYSTEM**Nov 15, 1995  
322 days to decisionK946319 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k946319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 28, 1994
Decision date	Nov 15, 1995
Days to decision	322 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946319/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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