

**K962106 SPLINE DENTAL IMPLANT SYSTEMS**Aug 29, 1996  
90 days to decisionK962106 · 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	<b>Calcitek, Inc.</b>
Location	Walker, MI, US
Contact	DONNA K HOWARD
510(k) history	21 submissions · 21 cleared · 1984-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962106/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 3, 2026