

K915597 BUR,DENTAL (76EJL)Feb 5, 1992
54 days to decisionK915597 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k915597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 13, 1991
Decision date	Feb 5, 1992
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915597/> Data sourced from FDA 510(k) public records (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. - Generated July 3, 2026