

K943604 INTEGRAL V BIOINTEGRATED DENTAL IMPLANT SYSTEM

Feb 8, 1996
563 days to decision

K943604 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k943604/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 25, 1994
Decision date	Feb 8, 1996
Days to decision	563 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

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k943604/>; 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