

K102822 IMPLANT-ONE SYSTEMJan 10, 2011
104 days to decisionK102822 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k102822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 28, 2010
Decision date	Jan 10, 2011
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Custom Dental Implants, Inc.
Location	Chseterland, OH, US
Contact	KAREN E WARDEN
510(k) history	1 submissions · 1 cleared · 2011-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102822/> 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 June 20, 2026