

K060957 MODIFICATION TO BLUE SKY BIO DENTAL IMPLANT SYSTEMMay 5, 2006
28 days to decisionK060957 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k060957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 7, 2006
Decision date	May 5, 2006
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Blue Sky Bio, LLC
Location	Grayslake, IL, US
Contact	MICHELLE VOVOLKA
510(k) history	16 submissions · 16 cleared · 2005-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k060957/>; 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 May 27, 2026