

K212785 Blue Sky Bio Multi One Implant System, Blue Sky Bio Long Implant System, Blue Sky Bio PEEK temporary abutmentsJun 30, 2022
302 days to decisionK212785 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k212785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 1, 2021
Decision date	Jun 30, 2022
Days to decision	302 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212785/> 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