

K250872 Bioline Dental Implant SystemJun 18, 2025
86 days to decisionK250872 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k250872/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 24, 2025
Decision date	Jun 18, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioline Dental Implant Systems, Ltd.
Location	Migdal Tefen, IL
Contact	Asher Ohayon
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Blackwell Device Consulting
Contact	Angela Blackwell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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