

K243002 MBA Biotech Implant SystemJun 6, 2025
253 days to decisionK243002 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k243002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 26, 2024
Decision date	Jun 6, 2025
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MBA Biotech Co., Ltd.
Location	Seongnam-Si, KR
Contact	Sung Youn Kim
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	April Lee

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

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