

K222946 Oneday Mini Implant SystemAug 23, 2023
330 days to decisionK222946 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k222946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 27, 2022
Decision date	Aug 23, 2023
Days to decision	330 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oneday Biotech Co., Ltd.
Location	Daegu, KR
Contact	Jae Hyun Song
510(k) history	2 submissions · 2 cleared · 2023-2024

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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