

K192294 I DoJul 31, 2020
343 days to decisionK192294 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k192294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 23, 2019
Decision date	Jul 31, 2020
Days to decision	343 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	I DO Biotech Co., Ltd.
Location	Daegu, KR
Contact	Jae-Hyung Song
510(k) history	1 submissions · 1 cleared · 2020-2020

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192294/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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