

K212364 BLT Dental Implant SystemAug 10, 2022
376 days to decisionK212364 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k212364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 30, 2021
Decision date	Aug 10, 2022
Days to decision	376 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bio Concept Co., Ltd.
Location	Changzhou, CN
Contact	Tianshui Li
510(k) history	3 submissions · 3 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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