

**K212702 IM/ST Fixture System**Oct 13, 2022  
413 days to decisionK212702 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k212702/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 26, 2021
Decision date	Oct 13, 2022
Days to decision	413 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guilin Fiteeth Medical Instrument Co., Ltd.</b>
Location	Guilin, CN
Contact	Jun Zhou
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
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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