FDA 510(k) Premarket Notification

K212702 IM/ST Fixture System

CLEARED

Oct 13, 2022
413 days to decision

K212702 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k212702/

SUBMISSION DETAILS

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

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

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