FDA 510(k) Premarket Notification

K240340 Surgical Drive System (Model: ES70, ES90, E8)

CLEARED

Jul 18, 2024
164 days to decision

K240340 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k240340/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Feb 5, 2024
Decision date	Jul 18, 2024
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guangdong Jinme Medical Technology Co., Ltd.**
Location	Foshan, CN
Contact	Ying Yang
510(k) history	4 submissions · 4 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**Guangzhou GLOMED Biological Technology Co., Ltd.**
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov