FDA 510(k) Premarket Notification

K210367 D-Laser Blue, D-Laser 16

CLEARED

Mar 10, 2022
395 days to decision

K210367 · Product code: **NVK** · Dental
Source: https://www.510kdatabase.net/k210367/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Feb 8, 2021
Decision date	Mar 10, 2022
Days to decision	395 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guilin Woodpecker Medical Instrument Co., Ltd.**
Location	Flintville, TN, US
Contact	Yang Yunfeng
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Fu Ailing

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