FDA 510(k) Premarket Notification

K212178 Root Apex Locator

CLEARED

Jul 20, 2022
373 days to decision

K212178 · Product code: **LQY** · Dental
Source: https://www.510kdatabase.net/k212178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Locator, Root Apex (LQY)
Date received	Jul 12, 2021
Decision date	Jul 20, 2022
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Foshan Coxo Medical Instrument Co., Ltd.**
Location	Foshan, CN
Contact	Yongjian Zheng
510(k) history	7 submissions · 7 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Beijing Believe-Med Technology Service Co., Ltd.**
Contact	Ray Wang

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