FDA 510(k) Premarket Notification

K222096 Endo Ultrasonic Activator

CLEARED

Mar 23, 2023
248 days to decision

K222096 · Product code: **ELC** · Dental
Source: https://www.510kdatabase.net/k222096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Jul 18, 2022
Decision date	Mar 23, 2023
Days to decision	248 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