

K192649 Endo MotorMar 12, 2021
535 days to decisionK192649 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k192649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Sep 24, 2019
Decision date	Mar 12, 2021
Days to decision	535 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Cicada Dental Instrument Co, Ltd.
Location	Foshan, CN
Contact	Juan Liu
510(k) history	4 submissions · 4 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	Guangzhou Keda Biological Tech Co., Ltd.
Contact	Jet Li

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

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