

K203320 Endo MotorMay 10, 2021
179 days to decisionK203320 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k203320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Nov 12, 2020
Decision date	May 10, 2021
Days to decision	179 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	Alex Wang
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Giselle Zhang

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

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