

K242514 Endo Motor (E-LITE MAX, E-LITE PRO, E-LITE INO)Apr 24, 2025
244 days to decisionK242514 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k242514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Aug 23, 2024
Decision date	Apr 24, 2025
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Rogin Medical Co., Ltd.
Location	Shenzhen, CN
Contact	Salon Chen
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Imd Medical & Drug Technology Service Institutions
Contact	Salon Chen

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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