

K231562 ELEC ENGINE (Model: ISE-170L)Jul 18, 2025
779 days to decisionK231562 · Product code: **EBW** · Dental
Source: <https://www.510kdatabase.net/k231562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	May 31, 2023
Decision date	Jul 18, 2025
Days to decision	779 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micro-Nx Co., Ltd.
Location	Daegu, KR
Contact	Lee Jong Kun
510(k) history	7 submissions · 7 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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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