

K201191 ELEC-LEDFeb 7, 2022
644 days to decisionK201191 · Product code: **EBW** · Dental
Source: <https://www.510kdatabase.net/k201191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	May 4, 2020
Decision date	Feb 7, 2022
Days to decision	644 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micro-Nx Co., Ltd.
Location	Daegu, KR
Contact	Jong-Kun Kee
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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