

**K202963 ELEC Master, ELEC Master Dual**May 5, 2023  
947 days to decisionK202963 · Product code: **EIA** · Dental  
Source: <https://www.510kdatabase.net/k202963/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Sep 30, 2020
Decision date	May 5, 2023
Days to decision	947 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mgnewton , Ltd.</b>
Location	Gyeongsan-Si, KR
Contact	Byoung-Wook Ahn
510(k) history	2 submissions · 2 cleared · 2022-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>LK Consulting Group USA, Inc.</b>
Contact	Priscilla Chung

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202963/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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