

**K212548 LUXEN CL Dental Liquid**Dec 6, 2021  
115 days to decisionK212548 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k212548/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Aug 13, 2021
Decision date	Dec 6, 2021
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Dentalmax Co., Ltd.</b>
Location	Cheonan-Si, KR
Contact	Park Seung Bum
510(k) history	3 submissions · 3 cleared · 2018-2024

**REGULATORY CONSULTANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212548/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026