

K241151 LUXEN 5GSep 30, 2024
158 days to decisionK241151 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k241151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Apr 25, 2024
Decision date	Sep 30, 2024
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentalmax Co., Ltd.
Location	Cheonan-Si, KR
Contact	Eunju Choi
510(k) history	3 submissions · 3 cleared · 2018-2024

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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