

K171585 LUXEN Zr, LUXEN SmileOct 31, 2018
518 days to decisionK171585 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k171585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	May 31, 2017
Decision date	Oct 31, 2018
Days to decision	518 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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