

K181597 Le'PenApr 1, 2019
287 days to decisionK181597 · Product code: **EBZ** · DentalSource: <https://www.510kdatabase.net/k181597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activator, Ultraviolet, For Polymerization (EBZ)
Date received	Jun 18, 2018
Decision date	Apr 1, 2019
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kmihh, Ltd.
Location	Kfar-Saba, IL
Contact	Or Ramot
510(k) history	1 submissions · 1 cleared · 2019-2019

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