

K183391 Novidia Universal BondSep 24, 2019
291 days to decisionK183391 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k183391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Dec 7, 2018
Decision date	Sep 24, 2019
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nobio , Ltd.
Location	Petach Tikva, IL
Contact	Inbal Beinglass Peled
510(k) history	5 submissions · 5 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	Nobio [C/O Promedoss, Inc.]
Contact	Shoshana (Shosh) Friedman

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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