

**K182921 Infinix Universal Composite**Sep 13, 2019  
329 days to decisionK182921 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k182921/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Oct 19, 2018
Decision date	Sep 13, 2019
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedoss, Inc.</b>
Contact	Shoshana Friedman

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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