

**K191991 Ezfil**Mar 5, 2020  
224 days to decisionK191991 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k191991/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jul 25, 2019
Decision date	Mar 5, 2020
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Meta Biomed Co., Ltd.</b>
Location	Elmhurst, NY, US
Contact	Suk Song Oh
510(k) history	21 submissions · 21 cleared · 2003-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191991/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 19, 2026