

**K190272 Bluephase PowerCure**Jul 3, 2019  
145 days to decisionK190272 · Product code: **EBZ** · Dental  
Source: <https://www.510kdatabase.net/k190272/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activator, Ultraviolet, For Polymerization (EBZ)
Date received	Feb 8, 2019
Decision date	Jul 3, 2019
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ivoclar Vivadent, AG</b>
Location	Amherst, NY, US
Contact	Sandra Cakebread
510(k) history	31 submissions · 31 cleared · 2004-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ivoclar Vivadent, Inc.</b>
Contact	Lori Aleshin

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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