

**K191382 IPS e.max CAD Abutment Solutions- extra systems**Aug 26, 2019  
95 days to decisionK191382 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k191382/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 23, 2019
Decision date	Aug 26, 2019
Days to decision	95 days
Third-party review	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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191382/> 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 14, 2026