

**K191448 Barrier Sleeves**Oct 8, 2019  
130 days to decisionK191448 · Product code: **PEM** · Dental  
Source: <https://www.510kdatabase.net/k191448/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	May 31, 2019
Decision date	Oct 8, 2019
Days to decision	130 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/k191448/> 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