

**K190537 BIO-C Sealer Ion+**Dec 12, 2019  
283 days to decisionK190537 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k190537/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Resin, Root Canal Filling (KIF)
Date received	Mar 4, 2019
Decision date	Dec 12, 2019
Days to decision	283 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Angelus Industria DE Produtos Odontologicos S/A</b>
Location	Londrina, BR
Contact	Paulo Sergio Calixto De Oliveira
510(k) history	5 submissions · 5 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190537/> 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 27, 2026