

**K180199 BIO-C TEMP**Jan 4, 2019  
345 days to decisionK180199 · Product code: **KIF** · Dental  
Source: <https://www.510kdatabase.net/k180199/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Jan 24, 2018
Decision date	Jan 4, 2019
Days to decision	345 days
Third-party review	No
Summary / Statement	Statement

**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/k180199/> 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