

**K163471 Kalitec Direct InSePtion™ MIS Fixation System**Mar 16, 2017  
94 days to decisionK163471 · Product code: **PEK** · Orthopedic  
Source: <https://www.510kdatabase.net/k163471/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Dec 12, 2016
Decision date	Mar 16, 2017
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kalitec Direct, LLC</b>
Location	Round Rock, TX, US
Contact	KEITH CANNAN
510(k) history	9 submissions · 9 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163471/> 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 16, 2026