

**K123396 I.FLEX BY TCS**Jan 10, 2013  
66 days to decisionK123396 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k123396/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Nov 5, 2012
Decision date	Jan 10, 2013
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Thermoplastic Comfort Systems, Inc.</b>
Location	Signal Hill, CA, US
Contact	MARLIN POSCA
510(k) history	3 submissions · 3 cleared · 2006-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123396/> 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 June 5, 2026